PATHOLOGY USER GUIDE

BEDFORD HOSPITAL

Effective from August 2011
(updates will be available on the electronic version available on Bedford Hospital website)

Version 1.0

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- Appointment for a Glucose Tolerance test

- Patient instructions for Collecting a 24 hour urine sample.

- Patient instructions for Collecting a 24 hour urine sample for HMMA (VMA) Catecholamines, Metadrenalins and 5HIAA

General information

Handbook preface

This manual outlines the pathology service offered by GSTS Pathology at Bedford Hospital NHS Trust.

The information provided includes reference values or interpretative data where relevant, specimen requirements and instructions for collecting specimens to comply with health and safety requirements.

Should you have queries in connection with any aspect of the pathology service, our staff will be pleased to discuss these with you. Errors, amendments and suggestions for the next edition should be brought to the attention of the pathology service manager.

This handbook is also available on Bedford Hospital website – www.bedfordhospital.nhs.uk

Key contacts

GSTS Clinical Director (Bedford)

Dr Fraser Mutch (fraser.mutch@bedfordhospital.nhs.uk)
01234 792325
Ext 4725

GSTS Pathology Services Manager (Bedford)

Mrs Gillian Flack (gillian.flack@bedfordhospital.nhs.uk)
01234 792156
Ext 4617

Customer Service Contact:

Anne Strong (anne.strong@bedfordhospital.nhs.uk)
01234 792628
Ext 4658

Results Hotline
01234 355122 Ext 4811

Further pathology contacts can be found within discipline specific sections.

Services

The pathology laboratories offer a comprehensive range of pathology services, fully supported by consultant-grade staff.

Service objectives

GSTS Pathology LLP – the UK's leading independent provider of pathology services – is a unique and innovative joint venture between Kings College Hospital, Guy's and Thomas' Hospitals NHS Foundation Trust and Serco plc. Bedford Hospital joined this partnership in December 2009.

GSTS is an exemplar of public private partnership in the health sector. The result is a unique clinically-led, customer-focused and scientifically-driven pathology service.

GSTS is transforming the way pathology is delivered, providing an end-to-end service that draws upon innovative processes and technology to improve outcomes for patients. Customers have access to one of the most extensive ranges of tests and support services. The company is a leading national diagnostic referral service, providing a wide range of specialist tests and routine services to support all healthcare organisations.

GSTS' customers include GPs, referring clinicians, the NHS and the private sector – both domestically and internationally.

Commitment to quality

All GSTS Pathology laboratories are currently registered or working towards registration with Clinical Pathology Accreditation (CPA) Ltd. The blood transfusion service is compliant with Medicine and Healthcare Products Regulatory Agency (MHRA). The cytology department within cellular pathology is compliant with Cytology External Quality Assurance.

Quality policy

This statement of purpose constitutes the quality policy for GSTS Pathology LLP which is an independent pathology provider registered with the Care Quality Commission.

The management system incorporates the requirements of the Health and Social Care Act, health and safety and environmental legislation and blood safety quality regulations, amongst others. The appropriate ISO standards are the underlying standard of operation for the medical laboratory services accredited by CPA (UK) Ltd and the United Kingdom Accreditation Service (UKAS).

Scope

GSTS Pathology is a clinically led, customer focused and scientifically driven full service pathology provider of accurate, timely and clinically useful prognostic, diagnostic and screening results, blood and blood products, with clinical advice to the NHS and private sector locally, nationally and internationally. Services include core pathology such as blood sciences, tissue sciences and infection sciences, typically delivered from each operational

site and specialised tests delivered from centres of excellence. Services participate in research, development and clinical trials.

Aims and objectives

The GSTS management system supports the business vision to be the leading pathology provider of high quality, cost effective pathology services and ensures that:

- GSTS Pathology has a business reputation based on safety, quality and customer service, using innovation to build a competitive advantage in chosen market sectors so that GSTS Pathology becomes the provider of choice.
- GSTS Pathology identifies its resource requirements through an effective management structure to ensure that risk and improvement opportunities are identified and acted on to protect or improve the health and safety of patients, staff and visitors.
- GSTS Pathology services operate above the minimum level of quality and compliance set by legislation and professional standards in the environment we operate.
- GSTS Pathology integrates its organisational structure, processes and procedures required to fulfil this policy and demonstrate improved quality outcomes.
- GSTS Pathology has an effective governance system that ensures accountability and provides internal and external assurance through reliable and relevant evidence.
- GSTS Pathology engages stakeholders to understand, meet and exceed their needs and requirements for patient safety, clinical effectiveness and operational performance.
- GSTS Pathology maintains an ethical culture and environment to underpin the business values. High standards of behaviour, staff engagement and empowerment with accountability are maintained to allow excellence in our services to flourish.

Quality improvement

GSTS has established continuous quality improvement as a business philosophy for all processes and services to support safe and effective patient care. GSTS Pathology continually monitors its activity, annually reviews this policy for its suitability and effectiveness and publishes a quality account which defines our quality improvement objectives. Services complete an annual management review to ensure objectives are monitored locally and changes or new systems, processes or procedures are implemented effectively. Satisfaction of users is seen as a key indicator of success in improvement of services. GSTS Pathology is proactive in managing its business risks and has plans in place to ensure service continuity in all events.

Workforce

GSTS Pathology will maintain a high quality flexible workforce that are committed, engaged, trained and supported to provide the highest level of service to our users in accordance with relevant good professional guidance. Through recruitment, induction and training, staff will be made familiar with this policy and relevant content and procedures of the management system. Each staff member holds a personal responsibility for the quality of the work that they perform. Competency assessment and appraisal is used to ensure ongoing capability and identify individual personal development.

Managers and supervisors provide effective leadership and create a culture and working environment that allows operational performance and change management to be achieved by staff that are empowered to make suggestions and take decisions.

Assessment and monitoring

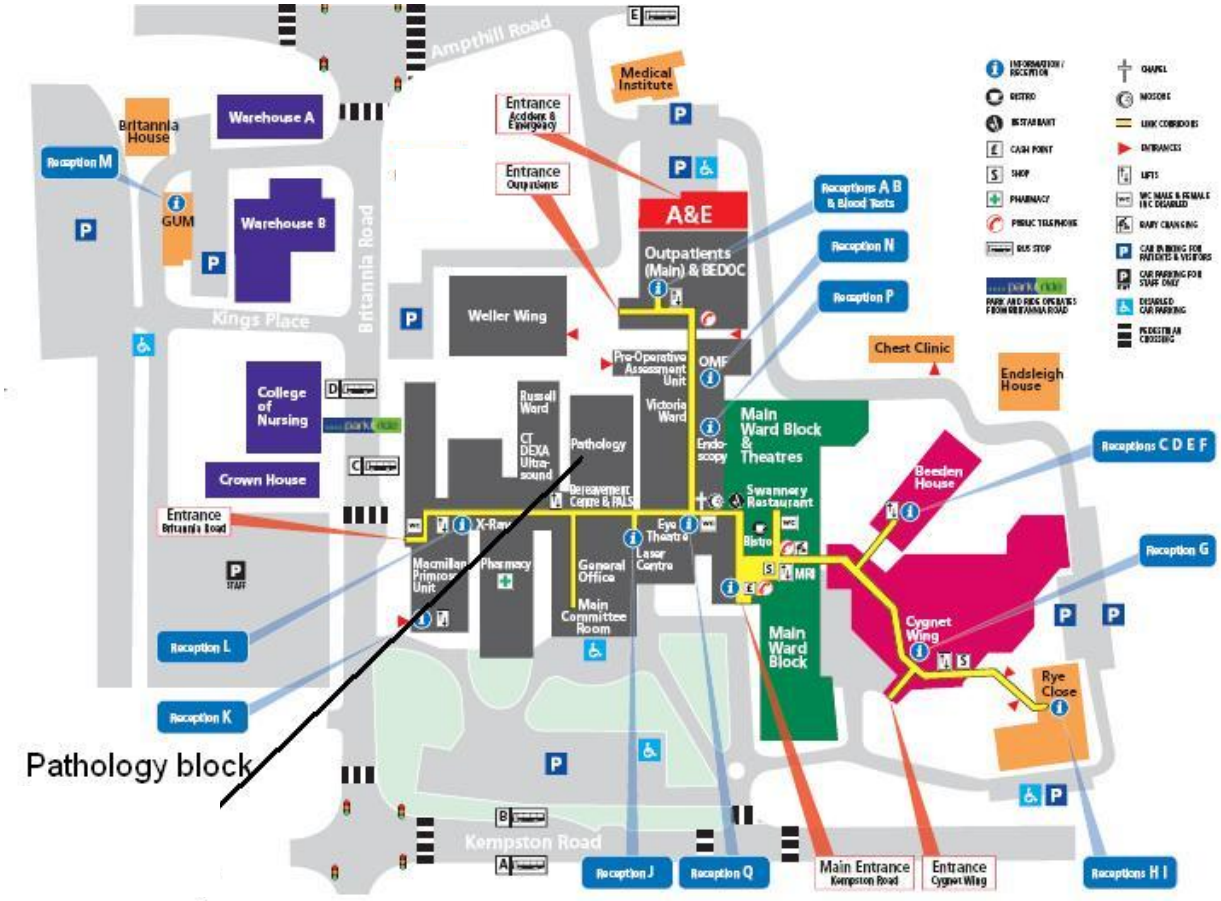
Key performance and quality indicators are used to enhance operational performance and remove variation from laboratory processes. Internal quality control and assurance with external quality assurance is used as part of the overall assurance mechanism along with clinical and internal audit to monitor adequacy of operating procedures and effectiveness of the quality system. Quality tools such as root cause analysis are used to ensure effective corrective actions are implemented. We recognise the confidentiality of information we hold on patients, donors and clients and allow accreditation and regulatory bodies appropriate access to the knowledge systems maintained to provide third party assurance to GSTS pathology and our stakeholders.

GSTS is registered with the Care Quality Commission (CQC) as an independent healthcare provider at all locations on which it operates for the provision of diagnostic and screening services and blood and transplant services.

Pathology block is located in the South Wing of Bedford Hospital

(see map below)

Pathology can only be accessed via swipe cards out of hours, but during working hours personnel can access the department from the hospital main corridor by pressing the pad on the left hand side of the main doors and reporting to pathology reception using the stairs or lift to the first floor. The pathology block does not have the facilities for any phlebotomy service. The pathology block (indicated on the map) contains the mortuary and bereavement service on the ground floor, clinical biochemistry, haematology and blood transfusion on the first floor, cellular pathology on the second floor and microbiology is located on the third floor.



Pathology opening hours

Please refer to individual departments

Out of hour's service

	Haematology/ Blood Transfusion	Biochemistry	Microbiology
Monday to Friday	**20.00 – 08.00**	**20.00 - 08.00**	**17.00 – 08.45**
Friday to Saturday	**20.00 – 09.00**	**20.00 – 08.00**	**17.00 – 08.45**
Saturday to Sunday	**12.30 – 07.00**	**12.30 – 08.00**	**12.00 – 08:45**
Sunday to Monday	**07.00 – 08.00**	**08.00 – 08.40**	**08:45 – 08.45**
Bank Holidays	**08.00 – 08.00 next day**	**08.00 – 08.00 next day**	**17:00 - 08:45**

Please be aware that there is only one member of staff for each discipline working during the hours listed above and that only a limited range of tests are available.

You are respectfully asked to:

- Restrict requests to tests which are **ESSENTIAL FOR THE IMMEDIATE CLINICAL MANAGEMENT OF THE PATIENT.**
- **Non-urgent work should only be sent during normal working hours.**
- Keep telephone enquiries to an absolute minimum.

Please note: Abuse of the system results in delay of other, genuinely urgent work.

Up to midnight haematology/blood transfusion/biochemistry samples will be processed at regular intervals. It is only necessary to contact the on-call BMS if the work is considered very urgent. After midnight it is **ESSENTIAL** to bleep the on-call biomedical scientist:

Clinical biochemistry **Bleep 432** [If no response please
Haematology/blood transfusion **Bleep 474** contact switchboard]

Both the clinical biochemistry and the haematology/blood transfusion biomedical scientist also carry DECT phones so that the **accident and emergency department** can alert the laboratory that samples need to be processed urgently or to enquire if results are available on their patients.

This DECT phone is **not** for use outside of the A&E department.

Between 17.00 and 20.00 haematology/blood transfusion may be contacted on extensions 4833/4653.

Microbiology **Contact via switchboard**

The on-call microbiology BMS is usually off-site and should always be contacted before urgent work is sent.

Work sent after midnight without bleeping the relevant personnel will be processed with the next urgent/batch of work.

ALL results produced out of hours will be telephoned and/or hard copy sent in the air tube to the requesting location and/or will be available on the ward reporting system available on all Trust computers connected to the Intranet.

Please LOOK on the ICE system before telephoning for results. CSF and antibiotic levels will be telephoned through to the requesting ward. These results will not be available on the ICE system until the next working day.

Consultant staff may be contacted via switchboard if clinical advice is required.

Requesting investigations

Request forms should be completed using ballpoint pen. All forms must be fully completed including patient's first name and surname, date of birth, hospital number, NHS number or address, sex, location for return of report (e.g. ward, GP surgery), risk status, consultant, name and bleep number of requesting doctor, date and time of specimen.

Request forms for specimen labelling

If a pre-printed label is used, please ensure that a label is placed also on all back copies of the request form.

It is essential that specimens are correctly identified otherwise:

- a patient may receive the wrong treatment
- a patient may not receive the treatment that they require

If request forms are being handwritten please ensure that they are legible.

A correctly completed request form must state:

- the patient's name
- date of birth
- hospital number or NHS number (if known)
- nature of the specimen
- date and time the sample was collected

- clinical diagnosis and relevant clinical signs/symptoms (including travel history if indicated)
- examination required
- Consultant caring for the patient
- Name and bleep or contact number of requesting doctor

Adequate clinical information and current drug treatment must be given to facilitate the interpretation of results, to establish the need to do further laboratory investigations on a specimen and to identify possible drug/test interactions, etc. Drug timing and dosages are also necessary to provide reliable therapeutic drug monitoring. If a test requires special collection conditions (e.g. fasting, timing) it should be clearly stated that the conditions have been met.

Please ensure that the correct consultant/GP code is used and that the destination for delivery of results is accurately and clearly stated. If request forms are not correctly and legibly completed then the laboratory reserves the right to cancel requests for the safety of patients.

We attempt to inform and advise users of such problems as they arise but may not always be able to contact those concerned.

Private work

All such work must be identified on the original request form. With private GP, outpatients and day-patient requests the appropriate invoicing address must be written on the form. The laboratory will advise on the procedures and charges.

Specimen collection

All specimens must be labelled with the patient's identification details i.e. name, date of birth, hospital number and the date and time of specimen collection. Accompanying request forms must contain the same information and the NHS number.

Samples for blood group and cross match must be hand written with surname, first name, date of birth, hospital number and signed by the person taking the sample.

All specimens must be transported inside a sealed polythene bag.

The person collecting the specimen is responsible for positively identifying the patient. Ideally, the patient should be asked to state their name and date of birth, and this should then be checked against the information on the patient's wristband. If the patient is unable to speak, their identity must be ascertained from their wristband.

The sample tubes must be labelled with ballpoint pen as soon as the samples are collected, and before leaving the patient or bleeding any other patient. Labelling must be clear and legible. Unlabelled or mislabelled specimens cannot be accepted, for the safety of patients and for the medico-legal protection of hospital staff.

Transport of specimens to the laboratory

Hospital sites

Samples should be sent to the laboratory by either the pneumatic tube system or arranging collection by a hospital porter. High-risk samples, blood gas samples, blood culture samples and any samples in formalin **must not** be sent through the pneumatic tube system.

General practitioner surgeries

Pathology samples are collected from surgeries by our courier service.

High risk specimens

Separate procedures are used in the laboratory for the safe handling and examination of some samples from patients known or suspected to have infections caused by certain pathogens (see below) that pose a risk to laboratory workers and others if handled incorrectly. It is the responsibility of the person taking such a specimen from a patient and sending it to the laboratory to ensure that the request forms and specimen container are labelled to indicate a danger of infection.

The request forms should be flagged with a self adhesive "high risk" label.

The request form must give sufficient clinical information to enable experienced laboratory staff to know what special precautions are necessary. In the interests of confidentiality, only the warning label need be clearly visible to others. Specimens from V.R.E. and M.R.S.A. positive patients do NOT require flagging.

Please see individual departmental guidelines for high risk specimen types.

To ensure valid results are obtained:

1. Avoid prolonged venous stasis when collecting blood. Consult tube guide for order of drawing samples.
2. Avoid contamination of sample with i.v. fluids.
3. Do not mix blood from one specimen container with another.
4. Ensure that urine collections are timed correctly and kept cool.
5. Fill in clearly what tests are required. Only ask for what you really need.
6. Avoid sending samples outside the routine working hours unless they are urgent and laboratory staff are expecting them.

Do not contaminate request forms with sample.

Special tests

Patients requiring phlebotomy for tests with ‘special’ requirements, see individual discipline section.

Reporting of results

Printed reports

Printed reports are sent out to hospital wards, hospital clinics and GPs daily.

Electronic reporting

Access to completed pathology results is available on all wards, departments and GP surgeries via the hospital electronic reporting system (Sunquest Anglia ICE).

Critical results

These will always be telephoned. GP requests marked urgent will be telephoned.

NB. Cytology and histology results do not get reported over the telephone.

Other services, complaints

Pathology is able to provide a range of services and information to wards, departments and GP practices. If you wish to discuss any service developments or require information relating to or derived from the pathology service then please contact the pathology services manager.

2. Clinical biochemistry

Key contacts

Telephone (Result Enquiries) Direct Lines 01234 792148 / 792160

Consultant Chemical Pathologist	Dr W S Wassif	Tel. 01234 792167	Ext 4661
Principal Clinical Scientist	Dr Louise Ward	Tel. 01234 355122	Ext 4657
Specialty Manager	Mr M Seaman	Tel. 01234 792165	Ext 4665
Laboratory		Tel. 01234 792166	Ext 4654
Out of hours		Tel. 01234 355122	Bleep 432
Secretary		Tel. 01234 355122	Ext 4625

Laboratory service

Routine services.

	Enquiries	Specimens
Monday to Friday	8.00 am – 8.00 pm	8.00 am – 5.30 pm
Saturday	9.00 am - 12.30 pm	9.00 am – 12.30pm Urgent specimens only

An out of hour's service is provided at all other times.

Specimens for all pathology departments should be left at specimen reception located on the 1st Floor of the pathology building. Access is via the hospital main corridor. A lift is available.

The laboratory provides a wide range of tests for the diagnosis and follow-up of patients, the results of most being available within 24 hrs of receipt of samples. Results from samples sent to specialist laboratories will take longer. Some of the in house specialised tests are done in batches and results are available within one week. Turnaround times are indicated in the assay service table.

Additional tests may be added to previously received samples up to a maximum of two days after receipt, subject to which test requested and sample integrity by the requesting physician phoning the laboratory.

Results of inpatient requests **marked urgent** will have a hard copy sent in the air tube and will be available on the ward reporting system as soon as processed. 'Critical' results, which need immediate intervention, will still be telephoned. Results of GP requests marked urgent will be telephoned.

The consultant chemical pathologist or principal clinical scientist is available on site during working hours (and by mobile phone at other times when on call). Doctors are encouraged to discuss the investigation and management of individual patients with the consultant chemical pathologist.

Sample requirements

Becton Dickinson (BD) Vacutainer System:

Most routine tests can be performed on:		3.5ml Serum Separating Tube SST (sand cap)
Except:-	Glucose	2 ml Fluoride Oxalate (grey cap)
	Glycated Hb:	2 ml EDTA (translucent lavender cap)

Fluoride Oxalate preservative (grey capped vacutainer) enables stable and accurate glucose measurements to be performed. Glucose measurements on unpreserved clotted serum samples can also produce accurate measurements if the sample is received and processed in the laboratory promptly (within two hrs). Therefore glucose will be analysed on clotted serum samples received from inpatients and South Wing phlebotomy including outpatients. Blood samples received from other locations are required to take a fluoride oxalate (grey/white capped vacuette) for glucose analysis.

Phlebotomy collections from small children and babies:

A 2 ml paediatric orange lithium heparin bottle can be used for these patients instead of an SST to yield a better volume of plasma for analysis, **except** for the following tests where an SST is necessary:

Anti tissue transglutaminase	Lithium
C1 esterase inhibitor	Protein electrophoresis
CEA	Vancomycin
Folate	Gentamicin

A minimum of 1 ml of blood is required for a routine biochemistry profile.

A 2 ml paediatric yellow fluoride oxalate bottle can be used for glucose analysis.

Some of the more specialised assays may require different samples - please contact laboratory before bleeding the patient. See assay services table.

Some important notes to help us give you a good service:-

1. Always ensure minimum delay between venepuncture and sending samples to the laboratory. Delays can cause changes in some analytes, particularly artefactual increases in serum potassium, phosphate and some enzymes.

   Haemolysis, lipaemia and icterus samples that may affect some analytes, will be noted on the report.

   Grossly haemolysed samples will not be analysed.

   However, if prompt delivery is not possible some tests are still valid on serum samples stored overnight (see list of tests below for further information).

   Further details of assay interference are available from the laboratory on request.

2. Please fill Vacutainer tubes (3.5 ml) even if few tests are requested – 'economising' on samples can cause processing problems and changes to some analytes. In general, multiple analyses can be performed on a single sample. Exceptions are indicated in the list of assays.

Pathology laboratories will not assay samples without the following minimum data set on **both** request card and sample container:

SURNAME
FIRST NAME
DATE OF BIRTH
HOSPITAL NUMBER OR NHS NUMBER

It is also desirable and frequently essential for results interpretation to include:

DATE OF SAMPLE
TIME OF SAMPLE
ADEQUATE CLINICAL INFORMATION

Inappropriately labelled or unlabelled samples will not be analysed.

A report will be issued stating-: "Unlabelled sample received, unsuitable for analysis. Consider repeat if still needed."

This will also be conveyed by phone for urgent requests.

Specimen transport

All specimens must be in blood collection tubes of approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers must be further contained within the specimen transport plastic bag with the request card kept separate in the front pocket. Leaking specimens are hazardous and may be destroyed. The pneumatic tube system may be used to transport specimens in accordance with the rule of use of the system. *(Air tube guide is available on the hospital intranet – online facilities).*

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations. Specimen transport bags, and request forms, which are supplied to the GPs, have an absorbent pad which will immobilise the entire leakage of a liquid specimen. These used in combination with the hospital courier service will ensure compliance with the regulations.

ASSAY SERVICES OFFERED BY CLINICAL BIOCHEMISTRY DEPARTMENT

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
ACE			15 days
ACTH	EDTA on ice	Send to lab immediately	21 days
Albumin			Same day
Alkaline Phosphatase (ALP)			Same day
Alpha fetoprotein (AFP)			3 days
Alpha-1-antitrypsin			10 days
Amino acid chromatography	Li Hep		10 days
Amiodarone		Pre-dose sample	10 days
Ammonia	EDTA on ice	Ring lab first	On receipt
Amylase			Same day
Aspartate Transaminase (AST)			Same day
Beta- 2- microglobulin			14 days
Bicarbonate			Same day
Bile Acids			8 days
Bilirubin (total & conjugated)			Same day
Blood Gases	Heparin syringe	Send on ice (not via pneumatic tube)	On receipt
Caeruloplasmin	Special bottle	Obtainable from lab	10 days
Calcium			Same day
Carbamazepine		Prior to oral dose	3 days*
Carboxyhaemoglobin	EDTA or Li Hep		On receipt
Carcino embryonic antigen (CEA)			3 days
CA 125			3 days
CA 199			3 days
CA 153			3 days
C1 esterase inhibitor			10 days
Cholesterol			Same day
Cholinesterase & phenotyping			21 days
Complement C3 & C4			3 days*
Copper	Special bottle	Obtainable from lab	10 days
Cortisol	Timed sample	See adrenocortical function protocol	3 days*
Creatine kinase (CK)			Same day
C reactive protein (CRP)			Same day
Cryoglobulins	Plain bottle	Arrange with lab	7 days
Cyclosporin	EDTA or Li Hep		3 days
DHEAS			14 days
Digoxin		6-8 hours post dose	3 days*
Electrolytes		See renal function	Same day
Estimated GFR (eGFR)		See guidance notes	Same day
Ethanol	Li Hep	Arrange with Consultant Chemical Pathologist	Same day
Ethosuximide		Prior to oral dose	7 days
Ferritin			Same day
Folate	SST or Red top only		Same day
Free light chains		Part of serum electrophoresis profile	14 days

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
Follicle stimulating hormone(FSH)		See infertility protocol	Same day
Fructosamine			8 days
Gastrin	Special tube – available in lab	Arrange with lab	14 days
Glucose	Flu Ox timed sample	State fasting/ random or if known DM	Same day
Glucose tolerance test (GTT)	Fl Ox timed samples	Arrange with phlebotomy (SW)	2 days
γ glutamyl transferase (GGT)			Same day
Haemoglobin A1c (glycated haemoglobin	EDTA	Available only for known DM	1 - 2 days
HDL cholesterol			Same day
Human chorionic gonadotrophin (HCG)			Daily but not week-ends
Human Growth Hormone			8 days
17 hydroxyprogesterone			10 days
Immunoglobulins (IgA, IgG & IgM)			3 days
Immunoglobulin IgE & RAST			21 days
Insulin / C peptide	Fl Ox & SST	Arrange with lab	15 days
Iron			Same day
Lactate	Fl Ox	Send to lab immediately	Same day
Lamotrigine			8 days
LDH			Daily, weekdays
Lead	Li hep or EDTA		21 days
Lipids (cholesterol & Triglyceride)		Fasting sample	Same day
Lithium		12 hrs post dose	Same day
Liver function tests (LFT) Bilirubin, AST Alk Phos & albumin			Same day
Luteinizing Hormone (LH)			Same day
Magnesium			Same day
Manganese	Special tube available from lab		15 days
17B Oestradiol		See HRT monitoring	2 - 3 days
Osmolality			Same day
Paracetamol			Same day
Paraprotein typing			14 days
Parathormone (PTH)			7 days*
Phenobarbitone		Prior to oral dose	3 days*
Phenytoin		Prior to oral dose	3 days*
Porphyrins		EDTA **	14-21 days
Progesterone		7 days before next cycle is due (day 21)	Same day
Prolactin			Same day
Prostate specific antigen (PSA)			Same day
Proteins (Total protein, albumin & globulin)			Same day
Protein electrophoresis			14 days
Renal profile (Na^+ K^+ & creatinine)			Same day

Test name (Tests highlighted in blue denote test sent away)	Sample SST unless otherwise stated	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
Salicylate			Same day
Sex Hormone binding globulin (SHBG)			2 - 3 days
Testosterone			2 - 3 days
Theophylline		Prior to oral dose	3 days*
Thyroglobulin			15 days
Thyroid stimulating hormone (TSH)			Same day
Thyroxine (Free T4)			2 days
Transferrin			Same day
Tri-iodothyronine (Free T3)			3 days*
Troponin T		6 hrs after onset of chest pain	Same day
Urate			Same day
Urea			Same day
Valproate		Prior to oral dose	3 days*
Vitamin B12			Same day
Vitamin D			14 days
Zinc		Special bottle obtained from lab. Must be a fasting sample	15 days

* Can be carried out urgently if agreed with consultant chemical pathologist/principal Clinical scientist.

** Protect from light. Please send both cells and separated plasma (it is not necessary to wash the cells).

Send away tests are indicated in blue.

Results marked as urgent that fall within the agreed guidelines will be issued to the requesting ward via the pneumatic tub system within one hour of receipt.

Test name (Tests highlighted in blue denote test sent away)	Sample	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
Urine			
Amino acid chromatography	Fresh MSU		10 days
Bilirubin	MSU		3 days
Calcium	24hr collection		Same day
Copper	24 hr collection	Special container required	12 days
Cortisol	24 hr collection		7 days
Creatinine clearance	24 hr collection	Requires 4ml SST blood	Same day
Cystine	24 hr collection	(no preservative)	15 days
Drugs of addiction (In house screen)	MSU		Same day
Drugs of addiction (Confirmation)	MSU		7 days
5 HIAA	24 hr collection	Acid preservative required – contact the lab for bottle	15 days
Homocystine	EMU		7 days
Metadrenalines (Phaechromocytoma screen)	24hr collection	Acid preservative required – contact the lab for bottle	17 days
Microalbumin	EMU		3 days
Mucopolysaccharides	MSU		19 days
Osmolality	MSU		Same day
Porphyrins	Fresh EMU*	Protect from light	14 days
Porphobilinogen (PBG)	Fresh EMU*	Protect from light	14 days
Potassium	24 hr collection**		Same day
Albumin Creatinine Ratio (ACR)	EMU		Same day
Sodium	MSU		Same day

EMU: Early morning urine
MSU: Midstream urine

* Protect from light

** 24 urine protein is not routinely available. We recommend ACR in accordance with NICE Guidelines. In non-diabetic, consider clinically significant proteinuria to be present if ACR is 30mg/mmol or more (this is approximately PCR of 50mg/mmol or more, or a urinary protein excretion of 0.5g/24hr or more). Heavy proteinuria should be considered present when the ACR is 70mg/mmol or more (PCR of 100mg.mmol or more, or a urinary protein excretion of 1.0g/24hr or more).

Test name (Tests highlighted in blue denote test sent away)	Sample	Special Requirements	Expected turn around time (routine tests are carried out the same day if received before midday)
Faeces			
Elastase	Small plain stool sample	Must be received in lab within 30 minutes	15 days
Porphyrins	Small plain stool sample	Protect from light	14 days
Sweat Tests			
Sweat chloride	Collection performed by paediatric department		Same day

Send away tests are indicated in blue.

Results marked as urgent that fall within the agreed guidelines will be issued to the requesting ward via the pneumatic tub system within one hour of receipt.

Add on tests are generally not recommended unless the additional tests are important for immediate patient management or a repeat sample will not be relevant e.g. a paracetamol level on an additional sample taken much later after the overdose. Laboratory staff who receive telephoned add on requests will inform the requestor to send an additional request card, stating that the sample is already in the laboratory and providing clinical information to justify the request. Specialist assays may be vetted for sanctioning by the consultant chemical pathologist or clinical scientist.

If other assays are required, please contact Consultant Chemical Pathologist Dr W. Wassif or Dr Louise Ward, principal clinical scientist to discuss.

The following hospitals are routinely used to refer specialist tests for analysis.

GSTS Pathology - London
Central Middlesex Hospital – London
St Bartholomew's Hospital – London
St Mary's Hospital – London
Royal Free Hospital – London
Hammersmith Group Hospitals - London
Protein Reference Unit – Sheffield
Medical Toxicology Unit – London
Addenbrooke's Hospital – Cambridge
Great Ormond Street Hospital for Children - London
King's College Hospital – London
UCLH Hospital – London
Selly Oak Hospital - Birmingham

GSTS PATHOLOGY CLINICAL BIOCHEMISTRY REFERENCE RANGES FOR ASSAYS CARRIED OUT ON SITE

Albumin	35 - 50 g/L
Alkaline Phosphatase (ALP)	Adult 30 - 120 iu/L 0 - 17 yrs 40 - 390 iu/L
Alphafetoprotein (AFP)	< 7 iu/mL
Alaninne Transferase (ALT)	0 -40 iu/L
Ammonia	Male 15 - 55 mmol/L Female 11 - 48 mmol/L
Amylase (Serum)	< 100 iu/L
Aspartate Transferase (AST)	10 - 50 iu/L
Bicarbonate (serum)	22 - 29 mmol/L
Bilirubin (Total) (conjugated)	3 - 20 µmol/L 0 - 5 µmol/L
Beta-2-microglobulin	0.80-2.20 mg/L
Blood Gases:	
PH pCO_2 pO_2 Bicarbonate CO_2 content Base excess Standard Bicarbonate % O_2 saturation	7.35 - 7.45 4.7 - 6.0 kPa 10.0 - 13.3 kPa 22 27 mmol/L 24 - 32 mmol/L $\pm$ 2 mmol/L 22 - 27 mmol/L No reference range
Calcium (serum)	>2 - 150 yrs 2.20-2.60 mmol/L 0 - 2 yrs 2.35 - 2.72 mmol/L
Corrected Calcium	$\pm$ 0.02 mmol/L of Calcium for every g/l variation from an Albumin of 40 g/L. eg. Ca 2.80 Alb 35 Corrected Ca 2.90 Ca 2.80 Alb 45 Corrected Ca 2.70 (Invalid if albumin is <20 g/L)
Calcium (urine)	2.5 - 7.5 mmol/d
Carbamazepine	4 - 12 mg/L

Carboxyhaemaglobin	< 1.5 % of Total Hb
Chloride	95 - 108 mmol/L
Chloride (sweat)	Less than 40 mmol/L
Cholesterol	See Lipid interpretation
C3 complement	0.75 - 1.65 g/L
C4 complement	0.20 - 0.65 g/L
CA 125	0 - 35 u/mL
CA 153	0-28 u/mL
CA 199	0-34 u/ml
CEA	0 - 4 ug/L
Cortisol(serum)	9 am 170 - 700 nmol/L 12 mn < 100 nmol/L -Random cortisol is of limited clinical use. If Cushing's Syndrome is suspected, we recommend overnight dexamethasone suppression test as the initial investigation. If adrenal failure is suspected a short synacthen test is indicated.
Creatinine(serum)	0 – 1 month 30 – 80 umol/L 1m – 6 years 15 – 40 umol/L 6 y – 12 years 25 - 60 umol/L Over 12 years 60 – 110 umol/L
Creatinine Clearance	80 - 120 ml/min
Creatine Kinase (CK)	Male: 40-320 iu/L Female:25-200 iu/L
C-Reactive Protein	< 5 mg/L
Cryoglobulins	Not detected
Digoxin	0.5-2.0 ugl/L
eGFR	See interpretive information in this document
Electrolytes (Na, K and Creatinine) Serum Urine	 See individual Test See individual Test

Ferritin	Male: 20 yrs + 30-400 µg/L Female: 15-50 yrs 15-150 µg/L 50 yrs + 30-400 µg/L
Free light chains	Kappa 3.3-19.4 mg/L Lambda 5.7-26.3 mg/L K/L ratio 0.26-1.65
FSH (Follicle Stimulating Hormone)	Male: 2.0 - 12.0 iu/L Female: Follicular 2.0 - 12.0 iu/L Luteal 3.0 – 9.0 iu/L Levels high mid cycle Post Menopause > 25.0 iu/L
Gentamicin	Refer to normogram for dosage interval. Antibiotic policy is available on the Trust intranet. For endocarditis patients only, maintain pre-dose <1mg/L and post dose (1-2 hours) between 3-5 mg/L
Gamma Glutamyl Transferase (GGT)	5 – 55 iu/L
Globulin	15 - 35 g/L
Glucose (sugar) plasma Serum CSF glucose	3.0 - 6.0 mmol/L 60 % of plasma glucose
Haematinics: Serum B12 and Folate	B12: >150 pg/mL Folate: > 4.6-18.7 ng/mL
Haemoglobin A1c (Glycated Hb, HbA1c)	< 53 mmol/mol (<7%) suggests good glycaemic control 53-64 mmol/mol (7-8%) suggests fair control, though improvement of glycaemic control is desirable. 64-75 mmol/mol (8.1-9%) suggests inadequate glycaemic control >75 mmol/mol (>9%) suggests poor glycaemic control
HDL Cholesterol	See lipid interpretation
ßHCG (human chorionic gonadotrophin)	Non pregnant 0-4 iu/L
Homocystine	Not increased
Immunoglobulins (IgA, IgG and IgM)	Adult IgA 0.5 - 4.0 g/L Adult IgG 5.0 - 14.0 g/L Adult IgM 0.5 - 2.0 g/L See Protein Electrophoresis SOP book for child ranges.
Iron	Male 10 - 30 µmol/L Female 9 - 27 µmol/L

Lactate	0.50 – 2.00 mmol/L
Lactate Dehydrogenase (LDH)	240 – 480 iu/L
LDL Cholesterol	See lipid interpretation
Lithium	0.50 - 1.20 mmol/L Suggested therapeutic range Therapeutic range of 0.5-0.8 mmol/L may be adequate in prophylaxis.
LH (Luteal Hormone)	Male 2.0 - 9.0 iu/L Female:Follicular 2.0 - 12.0 iu/L Luteal 1.0 - 11.0 iu/L Post menopause >12.0 iu/L Levels high at mid cycle
Magnesium	0.7 - 1.0 mmol/L
Microalbumin	Male <2.5 Female <3.5 mg/mmoL creatinine
Oestradiol	Premenopausal female 110 -1450 pmol/L, depending on stage of cycle. Untreated post-menopausal female: less than 110 pmol/L Although the test is of limited clinical value in the diagnosis of menopause. Male: less than 160 pmol/L
Osmolality (Serum) (Urine)	275 - 295 mOsmol/Kg. Interpret in light of clinical features,serum osmolity and random urine sodium.
Parathyroid hormone (PTH) (Calcium, albumin, phosphate & total protein also to be assayed)	15 - 65 pg/ml
Paracetamol (Serum) (Urine)	Not Detected Not Detected
Phenobarbitone	15 - 40 mg/L
Phenytoin	Adult 10 – 20 mg/L
Phosphate	0-1 mth 1.2-2.8 mmol/L 1-6 mths 1.2-2.1 mmol/L 6 mth - 1 yr 1.2-1.9 mmol/L 1-7 yrs 1.3-1.8 mmol/L > 7 yrs 0.8-1.5 mmol/L

Primidone	Assayed as phenobarbitone
Porphobilinogen	Customised Porphyria report
Porphyrins	Customised Porphyria report
Prolactin (+ Macroprolactin)	Male < 450 mu/L Female < 550 mu/L Customised report
Protein (Serum) (Urine) (CSF)	60 - 80 g/L <0.15 g/d < 0.4 g/L
Protein Electrophoresis	Normal Pattern
Potassium (Serum) (Urine)	3.5 - 5.3 mmol/L 25 - 125 mmol/d
PSA	0.5 – 4.0 ug/L Normal, although does not absolutely exclude a localised prostatic cancer. PSA is also raised in other conditions, e.g. BPH, prostatitis, prostatic infarction, UTI, transuretheralresection of prostate (TURP) and prostate biopsy. A rise of >20%/year refer for further investigation.
Progesterone	Levels of <20 nmol/L, probably non-ovulatory. Ovulation likely if level >30 nmol/L. These interpretations apply only for samples taken 7 days before the next cycle.
Rheumatoid Factor	< 30 iu/ml
Salicylate	Not detected
Sex hormone binding globulin	Male 15-55 nmol/L Female 20-120 nmol/L
Sodium (Serum) (Sweat) (Urine)	 133 - 146 mmol/L < 60 mmol/L Interpret in the light of clinical features + plasma and urine osmolality and serum sodium.

Testosterone	Male 9-29 nmol/L Female 0.2- 1.8 nmol/L
Testosterone/SHBG ratio Free Testosterone Index (FTI)	Male 25-90 Female 0.2 – 5.6 In males low FTI indicates androgen insufficiency In females high FTI indicates androgen excess.
Theophyline	Adult 8 - 20 mg/L Neonate 5 – 10 mg/L
Thyroxine (FT4)	12 –22 pmol/L
Tri-iodothyronine (FT3)	3.1 – 6.8 pmol/L
TSH (Thyroid stimulating hormone)	0.25 – 4.00 mu/L
Transferrin	23-43 ug/L
Troponin T	The following interpretive comments only apply if the sample is taken at least 6 hours after the onset of chest pain: <14 ng/L Myocardial damage may be ruled out. >= 50 ng/L Myocardial damage present. Consider cardiology opinion 14-49ng/L Borderline Troponin T concentration. It would be prudent to repeat test after a further 6 hours. If the clinical picture is that of acute coronary syndrome, consider cardiology opinion.
Urate (Serum) (Urine)	0.1 - 0.4 mmol/L 1.5 - 4.5 mmol/d
Urea (Serum)	2.5 - 7.8 mmol/L
(Urine)	250 – 600 mmol/d
Valproate	50 – 100 mg/L Some patients are effectively controlled with concentrations below 50 mg/L and others require concentrations far in excess of 100 mg/L
Vancomycin	Maintain dose between 5-15 ug/L. Antibiotic policy is available on the Trust intranet.

LIPID INTERPRETATION

Cholesterol		In patients with personal history of occlusive vascular disease, target Total Cholesterol should be less than 4.0 mmol/L
Triglyceride	Fasted sample	0.40 - 1.80 mmol/L
HDL Cholesterol		Ideally greater than 1.0 mmol/L
LDL Cholesterol	Calculated test. Valid if patient fasted and Triglyceride does not exceed 4.5 mmol/L	In patients with personal history of occlusive vascular disease, target LDL-Cholesterol should be less than 2.0 mmol/L
Chol/HDL Ratio		Ratio of < 5.00 reduces the risk of cardiovascular disease.

On call service

The following tests are available if requested:

Electrolytes and creatinine	CRP
Urea	Bilirubin on paediatric samples (total & direct)
Glucose	Calcium (inc albumin)
Amylase	Magnesium
Bicarbonate	Paracetamol
Chloride	Salicylate
CSF protein	LFT
CSF glucose	CK
Vancomycin	Lactate (grey/white topped vacuette)

Blood Gases & Carboxyhaemoglobin Other routine analytes may also be resulted on the interim report which is sent to the ward. Critical results will be telephoned to the requesting physician or to the ward.

Iron and Lithium for overdose cases.

Gentamicin will be analysed if the sample is between six to fourteen hours post dose and the patient is on an 'extended interval regimen', or they are on an alternative regimen.

Anti-epileptic drugs, theophylline and digoxin are not routinely available on call.

Unusual drug assays – not available – for information contact Medical Toxicology Unit, St Thomas' Hospital, Lambeth Palace Rd, London SE1 5EH. Telephone 0207 7188 8686/8690/8783.

Ethanol (dark green topped lithium heparin vacutainer sample) analysed by arrangement with the consultant chemical pathologist.

Osmolality – needs to be specifically requested by a doctor, ICU requests will be analysed on a Sunday between 08:00 and 19:00hrs

Insulin and C-Peptide (red topped vacutainer), will not be processed out of hours (send away tests) but will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP), an insulin request MUST be accompanied by a glucose request.

PTH (red topped vacutainer), will not be analysed out of hours but it will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP). A PTH request must be accompanied by a calcium request.

ACTH (2 x translucent lavender topped vacutainer), will not be processed out of hours (send away test) but it will be stored appropriately (requires immediate receipt by the laboratory for freezing ASAP). An ACTH request must be accompanied by a cortisol request (sand topped vacutainer).

Ammonia – on call staff in the laboratory need to be contacted, sample (lavender/white topped) needs to be taken on ice and received immediately to the laboratory.

For any other test the consultant chemical pathologist or principal clinical scientist on call needs to be contacted via switchboard.

Clinical Service

The department runs a metabolic clinic and has an active role in the management of patients with dyslipidaemias, porphyrias and other metabolic disorders.

Further information

Additional information, useful suggestions and guidelines of services provided by the clinical biochemistry department are described in the following section. (This is by no means a comprehensive list, but if there are any specific problems please phone the laboratory or consultant chemical pathologist to discuss).

Adrenocortical function

Random cortisol measurement is of limited clinical value. If hypersecretion is suspected (i.e. Cushing's syndrome) then we recommend that cortisol should be measured in a 9am blood sample (SST tube) collected after giving 1 mg of dexamethasone orally at 2300hr the previous evening. If hyposecretion is suspected (i.e. Addison's) then we recommend performing a short synacthen test.

Please note that prednisolone and hydrocortisone suppress the adrenal gland and interfere with cortisol assays. Please contact the laboratory or seek an endocrinological opinion if you need to investigate these patients.

Diabetes Mellitus (DM)

Random Blood Glucose

	Capillary Blood mmol/L	*Venous Plasma mmol/L*
Diabetes likely	≥ 11.1	≥ 11.1

Fasting Plasma Glucose

Diabetes likely	≥ 7.0
Impaired Fasting Glycaemia (IFG)	6.1 – 6.9

> If random plasma or blood glucose ≥11.1 or fasting plasma glucose ≥ 7.0 and the patient has symptoms (polyuria, polydipsia or unexplained weight loss), then further tests are unnecessary and DM is confirmed.
>
> If symptoms are not present, another raised fasting or random plasma glucose concentration is needed to diagnose DM.

Individuals with IFG should have their fasting plasma glucose checked annually. All those with a repeat non-diagnostic fasting plasma glucose (in the IFG range) should have oral glucose tolerance test (OGTT) to exclude/diagnose DM.

If in doubt an oral glucose tolerance test should be performed. A fasting glucose alone may not be diagnostic.

Oral Glucose Tolerance Test (OGTT)

Advise patient to fast for about 12 hours overnight following three days of unrestricted carbohydrate diet. 75g of glucose (in the form of Lucozade) is given and blood samples taken at 0 mins and 120 mins. **Pregnant patients will have an additional sample taken at 60 mins**.

Glucose meters should not be used for glucose assay during OGTT and a reliable laboratory glucose assay should be used to exclude/diagnose Diabetes Mellitus (DM) with confidence.

The phlebotomy department at South Wing (Tel: 01234 792160) will make appointments for OGTTs within one week if required.

Diabetes Mellitus is diagnosed if:

0 min	plasma glucose	≥ 7.0 mmol/l
120 min	plasma glucose	≥ 11.1 mmol/l

Impaired Glucose Tolerance is diagnosed if:

0 min	plasma glucose	< 7.0 mmol/l
120 min	plasma glucose	≥ 7.8 - < 11.1 mmol/l

Glycated Haemoglobin (HbA_{1c}) has no place in the diagnostic process nor in screening for DM. Glycated Haemoglobin is useful in monitoring treatment. As the life span of red cells is usually about 3 months we would like Glycated Haemoglobin assays requested not less than 10 weeks apart, except in pregnancy or under special circumstances.

Ante-natal

Random plasma glucose is checked between 26-28 weeks gestation. Glucose tolerance test is required for diagnosis/exclusion of gestational diabetes if random plasma glucose ≥ 6.5 mmol/L.

Pregnancy

It is advisable to refer all patients with pre-existing diabetes to the antenatal clinic at the hospital where adequate measures will be taken to monitor the patient during her pregnancy.

Microalbuminuria

All adults and children with known diabetes over the age of 12 years not previously diagnosed with microalbuminuria or proteinuria should be screened annually for microalbuminuria. Send a clearly labelled early morning urine to the Clinical biochemistry laboratory. The laboratory will measure the urinary albumin:creatinine ratio (ACR). Reference values are:

Males	<2.5mg/mmol
Females	<3.5mg/mmol

If the urinary albumin is found to be grossly elevated (>3800mg/L) then urinary total protein will be reported instead of microalbumin. The patient should be investigated for gross proteinuria in the usual way, to exclude urinary tract infection etc.

A normal microalbumin requires no further action until the next annual routine screen is performed. If the microalbumin is raised then the patient should be asked to provide a further two samples, preferably one week apart within the following three months which will be tested in sequence. Two positive results are required to make a diagnosis of microalbuminuria. If the second sample is positive (result above the reference range) then the third sample will not be analysed. Once a patient has been diagnosed with microalbuminuria, treatment should commence, and the patient's condition should be monitored by submitting urine samples for ACR assay every six months (only a single sample should be sent on each occasion).

Estimated Glomerular Filtration Rate (eGFR)

National Service Framework (NSF) on chronic kidney disease (CKD) recommends eGFR to monitor/diagnose CKD. Consider requesting eGFR as an alternative to creatinine clearance.

eGFR is not validated for use in children <18 years old, acute renal failure, pregnancy, oedematous states, muscle wasting disease states, amputees or malnourished patients.

Reference ranges

Estimated GFR (eGFR) ml/min/1.73m^2

>90	Indicates normal GFR, unless there is a structural abnormality or a functional abnormality such as persistent proteinuria or microscopic haematuria.
60-89	Does not indicate chronic kidney disease unless there is other existing laboratory/clinical evidence of disease.
30-59	Indicates moderate renal impairment. Consider monitoring eGFR 6 monthly.
15-29	Indicates established renal impairment. Consider monitoring eGFR monthly.
15-30 <15	Indicates established renal failure. Consider monitoring eGFR 3 monthly.

For African-Caribbean people only – eGFR should be multipled by 1.212

Further information can be obtained from: Department of Health. National Service Framework for Renal Services. Part Two: Chronic Kidney Disease, Acute Renal Failure and End of Life Care. 2005.

Available at : www.dh.gov.uk/renal.

HRT monitoring

Oestradiol assays are useful to monitor patients on implants. They are of little or no value in patients on oral preparations, as these are first conjugated in the liver, and hence may give a false indication of serum oestradiol levels. Furthermore, conjugated oestrogen preparation produce metabolites which interfere with oestradiol assays.

Serum oestradiol assay is available to investigate postmenopausal bleeding, suspected gonadal / hypothalamic / pituitary disorders and to monitor oestradiol implants.

Human Chorionic Gonadotrophin (hCG)

We do NOT provide this test for the routine diagnosis of pregnancy. If ectopic pregnancy is suspected then we recommend urgent referral of the patient to the accident and emergency department.

hCG is a useful marker to monitor molar pregnancies.

Menopause

We recommend only FSH as the appropriate test to monitor ovarian oestrogen secretion around the time of menopause. Serum oestradiol is not recommended for investigating menopausal symptoms.

Menopause can be identified with certainty a year or more after the LMP.

A wide variety of hormonal patterns of LH, FSH, and oestradiol can occur in the serum during peri-menopause, with raised FSH being the most consistent feature.

However, post-menopausal biochemical parameters are no guarantee of post-menopausal state.

Prostatic Specific Antigen (PSA)

Serum PSA values tend to increase gradually with age. It is not unusual to find values of up to 6.5 µg/litre in those over 70 years.

PSA values	Interpretation
0.5 - 4 µg/litre	Normal, although does not absolutely exclude a localised prostatic cancer
4 - 10 µg/litre	20-25% chance of cancer
10 –59 µg/litre	overall 66% of patients will have prostatic cancer
> 60 ug/l	Usually indicates metastatic prostatic cancer
A rise of >20% / year	Refer for further investigation

PSA is also raised in other conditions, e.g. BPH, prostatitis, prostatic infarction, urinary tract infection, urethral catheterisation, retention of urine, transuretheral resection of prostate (TURP) and prostate biopsy.

Despite the lack of specificity of PSA for prostate cancer, at present it is the best tumour marker for the disease. Follow up PSA tests are valuable to monitor the management of prostate cancer, and to monitor men with equivocal results.

It is normally recommended to wait at least 6 weeks after prostate biopsy or TURP before obtaining a serum PSA level.

Prostate cancer can progress very slowly and it is often said that more elderly men die with prostate cancer than from it. Perhaps PSA testing should only be considered for men with a life expectancy of 10 years or more.

Digital rectal examination (DRE) provides the cornerstone of the physical assessment for prostatic disease. A PSA should not be carried out without a DRE, and all patients with abnormal DREs should be referred to a urologist.

Changes in PSA usually take place fairly slowly and steadily and it is usually unnecessary to repeat PSA more frequently than every three months. A sudden rise in PSA to unexpectedly high levels should be confirmed before any action is taken as coincidental conditions such as prostatitis can occur in men with prostate cancer.

Finasteride, a 5-α reductase inhibitor used in the treatment of BPH, reduces PSA by 50% after 12 months of therapy. If a patient has a PSA level determined before starting finasteride and a subsequent level after 12 months does not fall below 75% of the pre-treatment level, it would be prudent to re-evaluate for prostate cancer.

Rhabdomyolysis

Request a serum Creatine Kinase (CK) and a renal profile. In acute rhabdomyolysis, there is severe muscle destruction and serum CK activities may exceed 50 times the upper limit of the reference range.

Subfertility investigations for females

First line biochemical investigations include FSH, LH, Prolactin, Testosterone and Sex Hormone Binding Globulin (SHBG) and Progesterone if the patient is menstruating.

Blood for FSH/LH should be taken during the follicular phase (days 1 - 5).

Progesterone assays are useful in detecting ovulation or anovulatory cycles. Best done during mid luteal phase (7 days before the next cycle is due). It has no place in other conditions.

Subfertility investigations for males / erectile dysfunction

The most useful biochemical investigations are serum FSH, LH, Testosterone, SHBG and Prolactin.

Tumour markers

Tumour markers are non-specific and are not useful as screening tests. High concentrations may occur in many benign conditions and in the absence of a tumour. If a tumour has not been identified it may be inappropriate to randomly request tumour markers to identify the primary tumour. Generally tumour markers are valuable in monitoring treatment of patients known to have malignancies and in follow up to detect recurrence.

CA 125

There are a variety of conditions in which raised values are obtained, e.g. endometriosis, pelvic inflammation etc. CA 125 is useful in monitoring treatment for carcinoma of the ovary. If there is a family history of carcinoma of the ovary (1 or more members of the family) or if ovarian mass is present then full screening procedures, including assay for CA 125, need to be done.

Clinical utility of other tumour markers

Other tumour markers useful in monitoring therapy and follow up include:α–fetoprotein (AFP, hepatocellular carinoma and testicular tumours), human chrionic gonadotrophin (hCG, choriocarcinoma and testicular tumours), carcinoembryonic antigen (CEA, colorectal cancer), CA19-9 (adenocarcinoma of pancreas) and CA15-3 (carcinoma of breast).

Therapeutic drug monitoring

Usual blood sampling times for oral preparations

Anti Epileptics	Collect just prior to the oral dose
Digoxin	Collect at least six hours post dose
Lithium	Collected approximately 12 hrs post-dose
Theophylline: Peak	* 2 hours after rapid release preparations * 4 hours after sustained release preparations
Trough	* Immediately before oral dose

Digoxin:

Change of therapeutic range and units of reporting, in line with National Pathology Harmonisation. Introduced on 06.05.09

Digoxin now measured in ug/L (Therapeutic range 0.9-2.2 ug/L).

Thyroid function tests

	Reference range
TSH = Thyroid Stimulating Hormone	0.25 – 4.00 mU/L
FT4 = Free Thyroxine	12 - 22 pmol/L
FT3 = Free Triodothyronine	3.1 – 6.8 pmol/L

Screening

TSH is the first line of investigation. If TSH is less than 0.60 mU/l, a FT4 will be organised.

If TSH is high, greater than 4.0 mU/L but less than 50.0 mU/L, a FT4 will be organised.

T3 toxicosis will be excluded where appropriate by assaying FT3 in those patients with suppressed TSH but normal FT4.

In patients with compensated/borderline hypothyroidism who are not on thyroxine replacement and are being monitored it is prudent to check thyroid antibodies and monitor TFT every two to three months.

Patients on replacement therapy

TSH will be performed in all patients.

FT4 will be organised in patients on thyroxine replacement with abnormal TSH

FT3 will be organised in patients on T3 replacement with abnormal TSH

It is usually unnecessary to monitor TFT more frequently than every two to three months. Less frequent long-term monitoring is needed in patients who are clinically and biochemically euthyroid.

Patients on suppressive therapy

TSH and FT4 will be assayed in all patients on suppressive therapy.

> Thyroid Function Tests may be misleading when requested in patients who are ill from non-thyroidal illness. It is usually unnecessary to screen for thyroidal illness in these situations and TFT should be organised when patient is well.

High risk samples

All ‘high risk’ samples should be clearly identified with a tick √ in the high risk box □ on the request card. The card, sample and bag in which the sample is transported in should have a ‘high risk’ sticker or a label clearly identifying ‘high risk sample’ on them to alert the user for additional precautions that need to be taken when handling the sample.

Overnight storage of blood samples

Every effort should be made to send the sample to the laboratory on the same day. However in exceptional circumstances, some useful information may be obtained after overnight storage of blood sample if the following are observed.

1. Fluoride Oxalate tubes (grey cap) for glucose or EDTA (translucent lavender cap) for HbA1c may be unaffected by overnight storage at room temperature.

2. Serum Separation Tube samples (sand cap) stored upright at room temperature i.e. 20 ºC overnight may well be suitable for some routine tests. However, artefactual elevation of serum potassium, phosphate and some liver enzymes are expected and make these assays unreliable.

3. However if Serum Separation Tube samples are stored in:

   a) a refrigerator (which may be close to 0 ºC)
   b) a hot place e.g. near a radiator or on a sunny window sill
   c) a car boot (which may be either hot or cold)

   Considerable changes to some analytes will occur, e.g. high potassium, high phosphate, low sodium and low calcium etc. etc. In short, results will be unreliable.

4. As storage conditions are beyond laboratory control and any changes to analytes cannot be quantified the laboratory will merely comment as follows:

   1) Date of specimen collection (if known) and date received will be documented.

   2) Haemolysed - this can be caused by poor or prolonged storage or difficulty with venepuncture and will cause increase in potassium, phosphate and some enzymes.

5. *If your surgery has a centrifuge the following procedure will enable SST samples to be stored in a refrigerator (4 ºC - 6 ºC) for 24 hours perhaps without significant change to routine analytes.*

Centrifugation of blood samples in SST tubes

1. Take blood sample from patient using normal Vacutainer procedure.
2. Mix blood by gentle inversion 6 times.
3. Allow sample to clot for 15–30 minutes.
4. Centrifuge for ten minutes at 3000 rpm.

(Time and speed may vary for different capacity centrifuges. The laboratory would be happy to advise; please telephone Mr M Seaman 01234 792165).

NOTE: The gel in the tube has now formed a barrier between cells and serum.

5. Store the sample upright in a refrigerator at 4°C - 6°C.

NB - **Never** centrifuge an SST more than once for any reason

3. Haematology

Key contacts

	Internal Ext.	Direct line (01234)
Haematology Results and General Enquiries	792150	4811
Consultant Haematologist	792145	2446/Bleep 264
Consultant Haematologist		2385
Consultant secretary	792145	2445
Mr A F Northern, Specialty Manager	792158	4662
Mr P Laundon, Blood Transfusion Manager	795764	4726/Bleep 331
Referral Laboratory	01234 355122	4668

Location.

The haematology and blood transfusion laboratories are located on the first floor of the pathology building on the South Wing site. Access is via the hospital main corridor. Phlebotomy services are **only** available in the out patient department, South Wing and Gilbert Hitchcock House at North Wing. Paediatric phlebotomy services are available from Riverbank children's ward. The laboratory is unable to offer phlebotomy services.

Opening times.

Routine services.

	Enquiries	Specimens
Monday to Friday	8.00 am – 8.00 pm	8.00 am – 5.30 pm
Saturday	9.00 am - 12.30 pm	9.00 am – 12.30pm Urgent specimens only

Specimens for all pathology departments should be left at specimen reception located on the first floor of the pathology building. Access is via the hospital main corridor. A lift is available.

Services available out of hours

The consultant haematologist is available via hospital switchboard for clinical advice and interpretation.

Urgent samples will always be processed by the department.

Only contact the on-call staff for any work after midnight or for any crossmatching request. All other specimens will be processed as timely as possible. The on-call biomedical scientist may be contacted via switchboard or on bleep 474.

User satisfaction and complaints.

The haematology department is pleased to receive constructive comments upon any aspect of its services.

A quality manual describing all aspects of the department's quality management system is available for inspection by users.

Turnaround times and sample requirements

Turnaround time for haematology and blood transfusion specimens may depend on the tests required.

It is the responsibility of the doctor to arrange for blood samples to be taken into the correct sample tube and arrive at the pathology department in good time to be analysed. GPs may send their patients to be bled by the phlebotomists Monday to Friday during normal working hours. Please note that after 12.30 pm waiting times will be considerably shorter. At present a satellite phlebotomy station is available at North Wing where arrangements are similar, except on Fridays when the station is closed.

A collection service for some GP practises who provide phlebotomy services is in operation.

Samples for **full blood counts** are normally analysed on the day of arrival and results returned to the requesting doctor the next morning following the evening computer print run. Results from work arriving on Friday will usually be delivered on Monday. Some Bedford practices will have their results delivered by hospital van whilst others will be posted. Samples taken after the van collection can be stored overnight at room temperature with no significant deterioration in quality. Results can also be sent electronically to GP practices via Anglia Sunquest ICE.

Urgent or very abnormal results will be telephoned as soon as possible. Relevant clinical information is of value in interpreting results e.g. in patients on chemotherapy. Failure to give this may generate unnecessary additional tests and delay the issue of results.

In the event of an **unexpected abnormal result** the laboratory will usually carry out further relevant haematological tests, e.g. Direct Coombs' test when the blood film suggests possible haemolysis. The consultant haematologists are available for advice or interpretation of results.

The following tests are performed and the results will normally be available within one working day.

Test	sample required
FBC	**EDTA** (1 X 3ml mauve top)
ESR	**EDTA** (1 X 3ml mauve top)
I M screen	**EDTA** (1 X 3ml mauve top)
Reticulocytes	**EDTA** (1 X 3ml mauve top)
Sickle-cell screen	**EDTA** (1 X 3ml mauve top)
R A test	**Serum** (1x 6ml red top)
Rhesus immunisation tests (incl. Kleihauer)	**EDTA** (1 X 3ml mauve top)
Malaria identification	**EDTA** (1 X 3ml mauve top)
Direct Antiglobulin test ("Coombs Test")	**EDTA** (1 X 3ml mauve top)
G 6 P D screening test	**EDTA** (1 X 3ml mauve top)
Coagulation Screening	**CITRATE** (1 X 3ml blue top)
INR	**CITRATE** (1 x 3ml blue top)
Atypical Blood Group antibody ID	**EDTA** (4 X 6 ML pink top)

The following tests are batched and performed on a batch basis and results are normally available within one week.

Haemoglobinopathy screening (for thalassaemia and abnormal haemoglobins)	**Serum plus 2 EDTA samples**
Blood Group & Antibody screen	**EDTA** (1 X 6 ml pink top)

The following tests are normally available only after arrangement with the haematologist:

Bone marrow aspiration and related cytochemistry

Trephine biopsy

Requests for other tests should be directed to either the clinical haematologists or specialty manager. Thrombophilia screening, HLA identification and cytogenetic studies are sent to specialist centres. Information regarding turnaround times and specific sample requirements can be obtained from the laboratory

Immunology testing is performed at another centre; samples are received in haematology for onward travel. Most immunology testing is performed from **SST** tube (gold top). Further details regarding Immunology may be obtained from the referral department in haematology.

Limitations and special precautions

Coagulation screens must be tested within four hours of being taken. Additional tests such as d-dimer may only be added within two hours from phlebotomy.

ESR may be added to a sample taken the same day

Blood film requests may be added to samples taken the same day

I.M screening may be added to samples taken the same day

Group and Save samples are kept for six days for crossmatching

Samples must never be stored in direct sunlight, carried on the parcel shelf of a car, or left near a radiator as these factors will directly interfere with results. Samples should reach the department on the same day. Where this in unavoidable contact the laboratory for specific storage instructions.

Completion of request forms.

All samples must be accompanied by a fully compliant request form. Information from the request card is transferred to the laboratory computer system. Illegible handwriting may lead to poor data transfer and incorrect filing of patient results.

Addressograph and other pre-printed labels must not be used on any sample sent to the blood transfusion department. They can however, be used on the request form.
Unsatisfactory blood transfusion request forms may in some cases be returned to the ward for correction and may lead to a delay in blood issue

Identification of high risk specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a **known or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

HIV 1 and 2
Hepatitis B virus
Hepatitis C virus
Brucella spp.
Salmonella typhi & paratyphi (typhoid)
Mycobacterium tuberculosis (TB)
HTLV 1 and 2

and the causative agents of:-

Anthrax
Rabies
Plague
Creutzfeldt-Jakob disease and vCJD
Yellow Fever

Sample labelling.

It is essential that specimens are correctly identified otherwise:

- a patient may receive the wrong treatment
- a patient may not receive the treatment that they require

All specimens **must** be labelled with:

- The patient's first name
- Surname
- Date of birth
- Hospital or NHS number
- The date/time of specimen.

Inadequately labelled specimens will not be examined and a report will be produced

"Inadequately labelled specimen received. Not processed. Please repeat."

Where there are clerical errors, omissions or quality issues with the sample, this will lead to immediate rejection by the laboratory.

Unrepeatable specimens

It is unlikely that samples for haematology are genuinely unrepeatable
In the unlikely case of unlabelled, unrepeatable specimens, the requesting doctor will be given the opportunity to identify the specimen. The doctor will be asked to sign to accept responsibility for identification.

Re-Labelling of samples for blood transfusion is not permitted.

Sample transport

All specimens must be in blood collection tubes of approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers must be further contained within the specimen transport plastic bag with the request card kept separate in the front pocket. Leaking specimens are hazardous and may be destroyed. The pneumatic tube system may be used to transport specimens in accordance with the rule of use of the system. *(Air tube guide is available on the hospital intranet – online facilities).*

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations.

Haematology transport bags, which are supplied to GPs, have an absorbent pad. These used in combination with the hospital courier service will ensure compliance with the regulations.

Normal ranges.

HAEMOGLOBIN g/dl	Men	13·0-18·0
	Women	11·5-16·5
	Child 3 months	9·5-13·5
	Child 1 year	10·5-13·5
	Child 3-6 yrs	12·0-14·0
	Child 10-12 yrs	11·5-14·5
MCV fl	Adult	76-96
	Child 3 months	95 (mean)
	Child 1 year	70-86
	Child 3-6 yrs	73-89
	Child 10-12 yrs	77-91
MCHC g/dl	Adult and Child	31-36
MCH pg	Adult	27-32
	Child	24-31
RDW	Adult and Child	11·5-14·5%
WHITE CELLS TOTAL		
	Adult	4·0-11·0
	Child 1 year	6·0-18·0
	Child 4-7 yrs	5·0-15·0
	Child 10-12 yrs	4·5-13·5
Neutrophils	Adult	2·0-7·5
	Child 6 yrs	2·0-6·0
Lymphocytes	Adult	1·5-4·0
	Child 6 yrs	5·5-8·5
Monocytes	Adult	0·2-0·8
	Child 6 yrs	0·7-1·5
Eosinophils	Adult	< 0·4
	Child 8 yrs	0·3-0·8
PLATELETS		150-400
RETICS		up to 2%
E.S.R.	Men < 50 yrs	1-7 mm
	> 50 yrs	2-10 mm
	Women< 50 yrs	3-9 mm
	> 50 yrs	5-15 mm

The International normalised Ratio (INR) is performed for routine Warfarin treatment control and APTT for the control of heparin therapy.

Normal therapeutic ranges are as follows:

		INR
Routine anticoagulation following DVT or PE		2·0 - 3·0
High risk patients (prosthetic valves and grafts, recurrent thromboembolism)		3·0 - 4·5
		APTT
Control of Heparin therapy (by iv pump) (LMW heparin is not monitored)		40 – 60 secs
Prothrombin Time	normal:	9.5 – 12.5 secs
APTT	normal:	23 – 31 secs
D-Dimer normal:	<220 ng/ml (for PE & DVT diagnosis)	
Clotting factor inhibitor tests	normal:	not present
Fibrinogen	normal:	2·0 – 4·0 g/l
Anti Xa assay (for control of LMWH)	Available for specific patients only.	

Seek advice from the consultant haematologist.

The advice of the consultant haematologist should be requested for patients with more serious coagulation defects - particularly if surgery is planned - or for investigation of bruising.

More detailed clotting studies, including factor assays (e.g. Factor VIII, Factor IX), are also available but only after discussion with a consultant haematologist.

Tests for thrombophilia and platelet function are sent to a reference laboratory. If required please refer to consultant haematologist.

Clinical haematology

Bedford Hospital provides a clinical haematology service covering all aspects of blood disease.

Inpatients

Inpatients are managed jointly with consultant physicians. Patients are admitted for blood transfusion, platelet transfusion, chemotherapy for chronic leukaemias, myeloma and some lymphomas, treatment of some coagulation disorders, treatment of thrombocytopenia, management of sickle cell crises and other haemoglobinopathy problems. An increasing number of patients can be managed as day cases. This would include simpler chemotherapy, i.v. immunoglobulin therapy, venesection and clotting factor replacement and blood transfusion.

Outpatient referrals

Outpatient referrals are all seen by a consultant haematologist. Advice on the suitability of a referral can be obtained by telephone throughout the working day. Suitable cases might include:

Iron deficiency

Iron deficiency which is unexpected or unusual - most cases will be due to bleeding which should be investigated unless obvious. Most such patients may be better served by direct referral to a physician for endoscopy etc. "Failed iron therapy" is often due to inadequate therapy (two to three months may be needed to get iron stores back to normal) - or due to an inadequate iron preparation (slow-release types e.g. Feospan and Ferrogradumet).

Unexplained macrocytosis

Unexplained macrocytosis (MCV>100) or persistently low B12 or Folate levels. Patients with severe macrocytic anaemia (Hb<8·0) should be referred immediately. Mild macrocytosis is quite common and is often due to excessive alcohol consumption - a high urate and GGT will confirm this in most. However in the elderly dietary folate deficiency seems to be common and macrocytosis is also a feature of the Myelodysplastic Syndrome (MDS) - see below. Other causes of a high MCV include liver disease, myeloma, COPD, hypothyroidism and treatment with cytotoxic drugs.

Unexplained anaemias

Other unexplained anaemias. Note that many chronic conditions and diseases lead to a mild to moderate anaemia which may be normochromic or mildly hypo-chromic and needs no investigation. Patients leading sedentary lives can often cope very adequately with moderate anaemia (Hb 8-10).

Neutropenia

Neutropenia in young patients may be due to a recent virus infection but if persistent or severe further investigation is essential. SLE can present in this way and tests for ANF may be appropriate.

Low platelet counts

Low platelet counts are increasingly common. Immediate referral is advised if very low (<20). Counts below 100 may require further investigation. Counts between 50 and 100 are unlikely to cause any bleeding/bruising but may be a problem for surgeons. Usually spontaneous bleeding does not occur until the count is significantly less than 20. Possible causes are: ITP, alcoholic and other liver disease, drug therapy (diuretics may be an important cause in the elderly). Incipient leukaemia and MDS are important causes but usually there will be other indications (neutropenia, anaemia, blasts). Pregnancy is often accompanied by mild thrombocytopenia in the last trimester - the principles already indicated apply.

The cause of a **high WBC** will usually be obvious but consider the following if in doubt:

Neutrophilia –	early stage of Glandular Fever steroid therapy previous splenectomy
Monocytosis –	often occurs in recovering phase of infection may be CMML (MDS)
Lymphocytosis –	viral infection previous splenectomy

Lymphocytosis

Lymphocytosis may be the first indication of underlying CLL, however unless there is marked lymphadenopathy or splenomegaly, anaemia and/or low platelets only observation is necessary. A FBC every two to three months will be adequate in most cases. Treatment is rarely needed in the early stage and many patients will not require intervention for many years particularly if the lymphocytosis was discovered by chance. Confirmation of C.L.L. requires Immunophenotyping. Now that differential counts are carried out routinely it is clear that transient lymphocytosis occurs in many “traumatic” situations and does not indicate bone marrow disease. If in doubt, repeat.

Lymphopenia

Lymphopenia is common in the elderly and also occurs after chemotherapy (sometimes persisting for many months) and in patients with chronic renal failure.It is often seen in HIV+ve people. **Chronic Myeloid and Acute Leukaemias** will usually be easy to diagnose, often by the laboratory first but if in doubt please refer.

Chronic and acute myeloid leukaemia

Chronic and acute myeloid leukaemias will usually be identified first by the laboratory but if in doubt please refer to the haematologist.

Myelodysplasia

Myelodysplasia or the Myelodysplastic Syndrome (MDS) seems to be increasing, possibly due to an increasingly aged population but also an increasing awareness of its subtleties. Characteristic changes are often seen on the blood film but many patients will have only anaemia/neutropenia/low platelets in varying degree. A bone marrow will often be diagnostic but in view of the limited therapy options at present it may be sensible to delay this until intervention is necessary – usually this will be the need for transfusion. The outlook in MDS is very variable.

All patients with **Hodgkin’s Disease or Non-Hodgkin’s Lymphoma (NHL)** require specialist attention, however a "tissue diagnosis" will usually be necessary. Isolated enlarged lymph nodes will require excision and referral without delay to a surgeon is essential. Other patients with probable lymphoma will almost certainly need complex diagnostic procedures and should be referred to the haematologist.

Myeloma

Myeloma may present with bone pain, symptoms which suggest a high calcium level (nausea, constipation, thirst, confusion), or just a high ESR (usually >100). Protein electrophoresis, urine analysis for protein or X-ray of the painful bone will often suggest the diagnosis. Bone marrow aspiration is mostly needed. Most patients can be treated in the OPD but hypercalcaemia is a medical emergency. Radiotherapy is often useful for bone pain.

Polycythaemia

Polycythaemia may be secondary to cyanotic heart disease, COPD or diuretic therapy. Occasionally it will be due to a renal tumour. Heavy smoking and alcohol consumption may lead to a high haematocrit but the level is not usually more than 0·55 (HB 18·0) Patients with levels significantly higher than this may have a myeloproliferative disorder (PRV) and should be referred. They will also often have high neutrophil and platelet counts and uric acid level. The spleen may be enlarged. Some will appear to have iron deficiency and the high Hb will not become apparent until iron therapy is given.

Thrombocythaemia

Thrombocythaemia may be secondary to a number of unrelated conditions. This "reactive" change often parallels the ESR. If the count is very high (>1000) it may be due to a primary bone marrow disorder. As with PRV there is a tendency towards TIA and stroke and these patients should be referred for investigation and therapy.

Anticoagulant clinics

Anticoagulant clinics are held Mondays to Thursdays. Patients are seen by the anticoagulant specialist nurse. Referrals are usually from local clinicians or provider cardiovascular units. Referrals from general practitioners are accepted if patients are being transferred from elsewhere and are already on therapy. A postal system which operates every day is available for patients with busy lifestyles who cannot attend the clinic and is also suitable for many other patients. Much valuable clinic time can be saved in this way.

A computerised system for both records and dosing has been introduced. This has allowed the present resources to cope with an increasing workload. Advantages are: reliable record keeping, improved statistical analysis, and more stringent follow-up of non-attenders. The dosing programme (not used for all patients) tends to be cautious and some patients may be recalled sooner than they would like. In some cases this is an advantage.

Interactions between anticoagulants and other drugs are a common problem. Safe alternatives should be chosen if possible. If there is no alternative patients should be asked to seek an earlier appointment at the clinic - remember that it will usually take several days for any change in the INR to occur after introducing a conflicting drug.

Generally patients with **Thrombophilia** (a thromboembolic tendency) will be referred by physicians or surgeons. However, it is now possible to identify some at-risk individuals using blood tests. Many of these will already be seen in other hospital departments but the following should be referred if not otherwise tested:

Unexpected PE/DVT in patients <45 yrs age
DVT/PE occurring in several family members
DVT/PE in young women on the "Pill"
Women with a clear history of recurrent miscarriage

The identification of the Factor V Leiden genetic defect has led to a great deal of public interest in thrombophilia. Much anxiety can be generated if inappropriate tests are carried out. In general the guidelines described above should be followed. If in doubt telephone the consultant haematologists.

Easy brusing

Patients with a serious defect of clotting will normally have been identified early in life. Easy bruising in later years however is common but in most patients no clear diagnosis emerges. Many will have taken aspirin or other drugs or preparations which affect platelet function and this possibility should be excluded. Others with a clear history of bruising or bleeding should be referred preferably after the following have been carried out:

FBC including platelet count
Clotting screen
Urea and liver function tests

Patients with **Haemophilia and other clotting disorders** will usually know where to obtain help. An advice service for Haemophilia is available for local patients and visitors.

The consultant Haematologist is willing to discuss clinical problems related to haematology throughout the working day (telephone numbers at top of section).

Refer to the hospital switchboard for advice on urgent clinical matters out-of-hours.

Referral laboratories

Where testing is not available on site, samples are referred to the following CPA accredited laboratories.

Laboratory address
Red Cell Immunohaematology ,North London BTS, Colindale Ave, London
Department of Clinical Biochemistry Kings College Hospital Denmark Street London
Department of Haematological Medicine Kings College Hospital Denmark Street London
Histocompatibility & Immunogenetics, NHS Blood and Transplant, 500 North Bristol Park, Northway, Filton, Bristol
Institute of Neurology, Queen Square, London
Cytogenetic department Kennedy-Galton Centre, Northwick Park Hospital Watford
Molecular Genetics Department Kennedy-Galton Centre Northwick Park Hospital Watford
East Anglian Medical Genetics Service Level 6 Addenbrooke's Treatment Centre Cambridge University Hospitals NHS Foundation Trust Hills Road Cambridge
Blood Coagulation Laboratory, Haemastasis Department of Clinical Haematology and Blood Transfusion Addenbrooke's Hospital Hills Road Cambridge
Immunology Laboratory Addenbrooke's Hopsital Hills Road Cambridge
Haemoglobinopathy Ref Lab Oxford Radcliffe Hospitals NHS Trust Oxford

3a. Blood transfusion

Specific Information for blood transfusion requests

Telephone requests always require confirmation by a valid form (plus sample where necessary).

Samples must include the following mandatory information:

- **SURNAME**
- **FIRST NAME**
- **HOSPITAL NUMBER (or EMERGENCY NUMBER or FULL ADDRESS or NHS No.)**
- **DATE OF BIRTH** (not age)
- **GENDER**
- **DATE /TIME OF SAMPLE COLLECTION /SIGNATURE (**person taking sample**)**

Request forms must include the following mandatory information:

- **THREE POINTS OF ID** (As per sample labelling)
- **GENDER**
- **WARD**
- **CONSULTANT**
- **DRS SIGNATURE**
- **DATE/TIME OF BLOOD OR BLOOD COMPONENT/PRODUCT REQUIRED**
- **REASON FOR REQUEST**
- **SPECIAL REQUIREMENTS** (where applicable)
- **HIGH RISK STICKER** (where applicable)

Failing to disclose special requirements such as CMV- neg or Irradiated products may result in major morbidity.

A bleep number and notification when a patient has atypical blood group antibodies is important. Failure to supply this information may delay blood issue

In emergency circumstances when the patient is unconscious or unknown, a **UNIQUE NUMERIC IDENTIFIER** (A&E number), **GENDER** & **DATE/TIME/SIG can be accepted.**

In the case of a suspected transfusion reaction or adverse transfusion event immediately telephone the lab (Ext 4833 or bleep 474 on-call) for advice/appropriate documents required.

Blood and blood product/component Issue.

Blood transfusion risks to the patient are significantly greater during the out-of-hours period. Therefore, it essential that non-urgent requests are limited during this period. This is in accordance with national guidelines (SHOT) and local Trust policy *(this is available on the intranet under policies and guidelines).*

Blood must ONLY be stored at 2-6° in a validated blood bank

Routine crossmatching takes about 65 mins but it is important to give as much notice as possible (preferably 24 hrs) due to possible blood shortages or the unexpected presence of atypical antibodies. 48 hrs minimum may be required when the patient is known to have atypical antibodies

Where the patient has had a recent group and negative antibody screen (<72hrs), blood can normally be issued safely using an abbreviated method within 5-10 mins.
The laboratory will automatically withdraw unused issued blood after 24-48 hrs unless an extension to this time has been requested by the doctor.

Anyone collecting or transporting blood or blood products must only do so if they have attended the mandatory Trust transfusion session within the last year. In order to enter p pathology an access card will be required and all persons collecting should only do so if given three points of patient ID (porter's collection slip), the product required and the number of units required.

Full and unambiguous traceability of blood and blood products is a legal requirement in accordance with the Blood Safety & Quality regulations (2005). The tear off section of the bag label must be completed as required and returned to the laboratory after transfusion. Where the label has not been returned, it will be the responsibility of senior ward staff to provide documented evidence. Failure to comply is a criminal offence and may be subject to disciplinary action.

Platelets must be stored 18-24°C and kept gently agitated. Collect from Lab immediately before use together with a platelet giving set.

Platelets are not stocked in the laboratory and any request must normally be made through the Clinical Haematologist. As all platelets are collected from the NHSBT at Colindale, North London, they are not immediately available. The journey takes at least 90 mins.

In cases of massive bleeding or trauma laboratory staff can order up to two units directly. If quantities greater than this are thought to be required contact the consultant haematologist.

Fresh Frozen Plasma (FFP) and Cryoprecipitate are stored at -40°C and will be thawed in quantities of one unit at a time except for massive bleeding or trauma where two may be issued.

In cases where multiple units are being transfused, telephone the Transfusion Lab (Ext 4833) 15 mins before the next unit is required to allow time for defrost. Transfusion of these packs must ideally be completed within 4 hours for maximum therapeutic effectiveness. Where there are unavoidable delays, FFP may be given up to 24 hours after thawing if kept in a validated blood bank at 2-6*C.

Anti-D immunoglobulin (1500iu & 250iu) is kept in the delivery suite blood bank. A small contingency stock is retained in the lab.

This product is for eligible RhD NEGATIVE patients only and must not be given unless indicated by appropriate laboratory tests.

All anti-D removed for use must be entered in the Anti-D register next to the blood bank

200 g/L Human Albumin Solution (H.A.S) is only available on request, laboratory staff can issue up to 400ml per patient. Where a greater volume is anticipated, contact the consultant haematologist.

50 g/L H.A.S is stocked in minor quantities in some satellite blood banks. Large volumes can be collected directly from the laboratory.

Details must be written in the appropriate register.

Beriplex (PCC) is only available after discussion with the consultant haematologist. It is available in 500iu & 250iu packs. A fully compliant request card is required and details must be recorded in the blood bank register.

4. Microbiology

Key contacts

Consultant Microbiologist: Dr Simantee Guha

Direct line: 01234 795845
Internal extension: 4603
e-mail: Simantee.Guha@bedfordhospital.nhs.uk

Specialty Manager: Guy Humphrey

Direct line: 01234 792208
Internal extension: 4610
e-mail: guy.humphrey@bedfordhospital.nhs.uk

Bacteriology results and general enquiries

Direct line: 01234 795913
Internal extension: 4703/4708

Serology results and enquiries

Direct line: 01234 795913
Internal extension: 4814

These notes are provided for clinical staff using the microbiology laboratory; they are not intended to be a complete or authoritative document but merely a guide to some of the services available. If you need further information about specimens, availability or suitability of tests, interpretation of results, or any other matter relating to the microbiology service, please phone the department. Laboratory staff will be pleased to help.

Opening hours

	Enquiries	Specimens
Monday – Friday	8.45am – 5pm	8.45am – 4.30pm
Saturday	9.00am – 12.00pm	9.00am – 11.00 am

Specimens for all pathology departments should be left at specimen reception located on the first floor of the pathology building. Access is via the hospital main corridor. A lift is available.

Specimens and tests

Request forms for specimen labelling

If a pre-printed label is used, please ensure that a label is placed also on all back copies of the request form.

It is essential that specimens are correctly identified otherwise:-

- a patient may receive the wrong treatment
- a patient may not receive the treatment that they require

If request forms are being handwritten please ensure that they are legible.
A correctly completed microbiology request form must state:

- the patient's name
- date of birth
- hospital number or NHS number (if known)
- nature of the specimen and the site from where it was taken
- date and time the sample was collected
- clinical diagnosis and relevant clinical signs/symptoms (including travel history if indicated)
- date of onset of symptoms (vital for serological tests – sample may not be processed without this information)
- examination required
- names of any recent, current or intended antibiotics
- Consultant caring for the patient
- Name and bleep or contact number of requesting doctor

Inadequately labelled specimens will not be examined and the report will be produced :
Inadequately labelled specimen received. Not processed. Please repeat.

Unrepeatable specimens:

In the case of unlabelled, unrepeatable, specimens such as CSF; blood cultures; pleural fluids etc the requesting doctor will be given the opportunity to identify the specimen. The doctor will be asked to sign to accept responsibility for identification.

Specimen transport

All specimens must be in blood collection tubes of approved, leak-proof primary containers as supplied by the laboratory. Lids must be firmly affixed to prevent leakage. Primary containers must be further contained within the specimen transport plastic bag with the request card kept separate in the front pocket. Leaking specimens are hazardous and may be destroyed. Please ensure that the outside of the container is not contaminated by the specimen at the time of collection. Contaminated containers are hazardous and may be destroyed.

The pneumatic tube system may be used to transport specimens in accordance with the rule of use of the system. *(Air tube Guide is available on the hospital intranet – online facilities).*

Specimens transported by road are classified as dangerous goods and must be packaged and labelled in accordance with the Carriage of Dangerous Goods regulations.

Microbiology transport bags, attached to the request forms, which are supplied to GPs, have an absorbent pad. These used in combination with the Hospital courier service will ensure compliance with the regulations.

Identification of high risk specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a **known or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

HIV 1 and 2 *Salmonella typhi & paratyphi*
Hepatitis B virus *Mycobacterium tuberculosis*
Hepatitis C virus HTLV 1 and 2
Brucella spp.
and the causative agents of:-
Anthrax Creutzfeldt-Jakob disease
Rabies Yellow Fever
Plague

Hazard group 4 biological agents

Specimens known or suspected to contain biological agents in Hazard Group 4 **MUST NOT** be sent to the laboratory without discussion with, and the permission of, the consultant microbiologist. This includes the causative agents of Viral Haemorrhagic Fevers (Lassa Fever, Ebola Fever and Marburg Disease)

Test repertiore

- Microbiology test repertoire
- Urine culture
- Stool culture
- Investigations for genital tract infections
- Blood culture
- CSF examination
- Specimens from other normally sterile sites
- Wound infections
- Eye, ear, throat and oral Infections
- Lower respiratory tract Infections
- Fungal infections
- Culture for Mycobacteria spp
- Antibiotic assays
- Serology

- Screening for congenital infections
- Chlamydia trachomatis antigen detection

If any tests other than the listed ones are required please contact the laboratory.

Urine culture

Mid Stream Urine: should be collected in a sterile container.

Clean catch urine: In young children clean catch specimens are preferable to bag urines which are almost always contaminated by perineal flora.

Supra-pubic aspirates: may be necessary in children to confirm a urinary tract infection.

CSU: send CSU only if infection is suspected, colonisation of the catheter is fairly common and does not require treatment.

Pad Urine: The limitations of pad urine are as follows:

- Cell count cannot be ascertained on pad urine samples
- Specimen should be collected from the pad without delay or will be contaminated with perineal flora giving false positive results.

If the specimen cannot be sent promptly to the laboratory it can be stored overnight in a specimen fridge or in a cool place.

Please Note: Specimens will not be examined if undated or inadequately labelled, efforts will be made to determine the date but if this is not possible or there is uncertainty over the date it will be discarded as erroneous results can occur.

Turnaround time – one to two working days.

Stool culture

Please state if:

- the patient has returned from abroad
- food poisoning is suspected
- the patient is on antibiotics or has received some in the last four weeks

1. Specimens from the community will be investigated routinely for:

- *Salmonella*
- *Shigella*
- *Campylobacter spp*.
- Verotoxic *Escherichia coli* (*E. coli* 0157/VTEC)
- Parasites
- *Clostridium difficile* **on request**

Extra investigations for other enteric pathogens are performed based on the age of the patient, the clinical picture, and travel history.

If parasites are of particular concern send three separate specimens (as parasites may be intermittently excreted) requesting a concentration for ova, cysts and parasites.

Threadworms, *Enterobius vermicularis* investigation*:* A sellotape slide is the most appropriate specimen. See section on *Specimen requirements & containers* below.

Rotavirus, Adenoviris investigation: A test for the detection of rotavirus and adenovirus antigen is available, and is routinely performed on all stools from children of five years or less in age.

2. Specimens from the hospital:

1. Specimens from patients will be routinely tested for:

- *Salmonella*
- *Shigella*
- *Campylobacter spp*.
- Verotoxic *Escherichia coli* (*E. coli* 0157/VTEC)
- *Clostridium difficile*

And any other tests requested.

Samples will NOT be processed if :

- A previous positive result was reported within 28 days of new request
- If clearance of *C. difficile* toxin is requested

If additional investigations are required they MUST be requested on the laboratory form.

Outbreak investigations:

Outbreaks from the community should be reported to the Health Protection Unit on 01462 705 300 who will organise samples after liaison with the laboratory

Hospital outbreaks must be reported as soon as possible to the infection control team who will give advice on specimen submission. Bleep 422, 030 or 301.

Turnaround time – one to two working days.

Preliminary result maybe available earlier.

Faecal occult blood

To avoid false positive results in this test it is important that an appropriate diet is followed prior to collection of the specimens. Copies of the instructions are available to patients from the department of microbiology or at pathology reception.

Instructions for collecting stool samples for testing for faecal occult blood

1. For three consecutive days, and whilst collecting the specimens of stools, eat no red meat, red meat extracts or green vegetables.

On second day take a mild purgative.

2. On fourth day collect a small portion of stool and place in a specimen pot.

3. Label with name and date and mark bottle "Specimen 1".

4. Collect specimens from next two stools and label as above, marking them "Specimen 2" and "Specimen 3" respectively.

5. Send the specimens all together to the Microbiology Department or Pathology reception at South Wing with an accompanying completed microbiology request form.

Copies of these instructions for patients are available from the Department of Microbiology or at Pathology Reception.

There is no evidence to show that iron salts such as ferrous gluconate or ferrous fumarate interfere with the test by producing false positives, but it is recommended that patients be kept off oral iron for at least two days prior to collecting the specimens.

Turnaround time – one working day

Investigations for genital tract infections

Vaginal discharge	Adult: High vaginal swab Child: Low vaginal swab
Suspected PID	Cervical and Chlamydia swab
Urethritis	Urethral swab and Chlamydia swab

Chlamydia Samples: Full instructions on the correct sampling technique are given with the Chlamydial swab, which may be stored in the fridge overnight after collection.

Bacterial culture: Where *Neisseria gonorrhoeae* is a possibility, specimens must never be refrigerated, as this organism will die and the diagnosis be missed. Ideally such swabs should be cultured immediately.

Where a sexually transmitted disease is suspected, it is recommended that the patients are referred to the department of genito-urinary medicine for follow up and contact tracing.
Turnaround time – one to two working days.

Blood culture

Blood cultures must be transported, by porter, to microbiology within an hour of collection. This may be done 24 hours a day.

General practice: blood culture is available to general practitioners, although rarely indicated in the community. Please discuss the case with the laboratory and request the appropriate culture bottles.

To collect blood for culture using the BACTEC automated blood culture system:

- Wash your hands
- Clean the venepuncture site with an alcohol wipe and allow to dry. Do not touch the venepuncture site again.

- Remove the flip off tops from an aerobic (blue/silver top) and an anaerobic (mauve/deep pink top) bottle
- Clean the rubber diaphragm on each bottle with an alcohol wipe and allow to dry
- Collect blood aseptically and inoculate 10 mls into the aerobic bottle and then 10 mls into the anaerobic bottle. Please note 8 to 10 mls is the optimum amount for each bottle. If blood is being collected for other tests, **always** inoculate the blood culture bottles first.
- Label each bottle with the patient's name, ward, date and time of collection. Do not use a patient identification label.
- Remove the detachable bar code labels from the bottles and stick onto the request form.
- Fill in the microbiology request form giving full clinical details, including antibiotics, and place both bottles in the accompanying plastic bag before sending it **immediately** to pathology reception for incubation
- Do not worry about the 'bits' in the aerobic bottle - this is resin designed to increase the yield of pathogens by absorbing antibiotics that may be present in the blood

In paediatric practice, where it may be difficult to obtain up to 20mls of blood, the silver topped PEDS PLUS/F single bottle system can be used. These bottles take between 1 and 3 mls of blood. In older children it is preferable to use the two-bottle system (as above) to increase the potential yield of significant pathogens.

Blood cultures must be taken **immediately** to pathology reception on the first floor. They MUST be incubated as soon as possible. **Out of hours** the blood cultures MUST be put in the blood culture incubator situated in the lift lobby on the third floor as soon as possible after collection.

Please note All blood cultures should be collected at the time the patient is ill and about to commence antibiotics to maximise the chance of isolating the pathogen involved.

For investigation of Sub-acute Bacterial Endocarditis (SBE), 3 sets of blood cultures, collected 20 minutes apart, should be sent.

Please include arrangements for contacting the ‘out of hours’ GP service should the blood cultures become positive at the weekend or during the evening, i.e. telephone number of the GP ‘out of hours’ service.

Turnaround time – Incubated for minimum five days, or, when indicated, up to three weeks. Any positive results telephoned immediately including at weekends. A negative report will be issued at 48hours after receipt into the laboratory

Cerebro-spinal fluid (CSF)

CSF is always treated as an urgent specimen. The CSF should be sent **immediately** to the Microbiology laboratory for a cell count, gram stain and culture, together with a blood culture. Stains for mycobacteria, cryptococcus etc will be performed as necessary or if requested.

The following specimens should also be sent to the chemical pathology laboratory:

1 sterile universal (approximately 0.3ml CSF) for protein estimation
1 fluoride oxalate bottle (approximately 0.2ml CSF) for glucose estimation
1 fluoride oxalate bottle (blood) for blood glucose estimation.

In suspected meningitis please send :

Blood in EDTA bottle to microbiology for PCR test for meningococcus and pneumococcus
Blood culture set
Throat swab for MC&S
Urine for pneumococcal antigen test
In suspected viral meningitis/encephalitis send:
CSF for viral PCR for VZV, HSV and enteroviruses, (at least 1ml is required by the reference lab)

Turnaround time – The cell count and gram stain will be telephoned to the clinician as soon as they are available.

Culture result available one to two working days after receipt.

Preliminary result maybe available earlier.

Wound infections

Pus samples**: If frank pus is available, always send this in a sterile universal container and not a swab** with pus on it.

Tissue: should be sent as a priority sample, placed in a sterile container and sent to the laboratory.

Wound swabs: Any chronic ulcers should be cleaned with sterile water and swabbed to avoid colonising flora.

Animal bite or scratch acquired outside the UK: please discuss the patient with the public health doctor on call via switchboard immediately if anti-rabies treatment indicated.

Turnaround time – Result available one to two working days after receipt.

Eye, ear, throat and oral infections

Eye swabs from neonates: are cultured for appropriate pathogens including *Neisseria gonorrhoeae* and thus it is important that such specimens reach the laboratory promptly after collection. Examination for *Chlamydia trachomatis* is also indicated in a neonate with a purulent eye discharge (use the swabs designated for the detection of *C. trachomatis* from the male genital tract).

Throat swabs: are cultured for haemolytic streptococci and *Corynebacterium diphtheriae*.
If culture for *Candida sp*. or other occasional pathogens is required, please state this clearly on the request form.

Per-nasal swab: If whooping cough is suspected special swabs may be required.

Turnaround time – Result available one to two working days after receipt.
Preliminary result maybe available earlier.

Lower respiratory tract infections

Sputum: Salivary specimens will not be cultured. Do not forget the possibility of tuberculosis (see *Mycobacteria, Microscopy & culture* - below).

If atypical pneumonia is suspected, please send:

- Sputum for Microscopy Culture & Sensitivity (MC&S) and *Legionella* culture
- Blood in a plain tube for atypical pneumonia serology will be sent to the reference lab for a baseline respiratory virus screen including mycoplasma, but specific requests must be made with clinical details for legionella, mycoplasma and Q fever serology. A second sample may be indicated in convalescence to detect a 4 fold rise in antibiody and/or a rise in IgM to be diagnostic.
- Urine sample for legionella antigen is a quick diagnostic test in acute legionnaires disease

Broncho-alveolar specimens: Will be cultured for routine pathogens, *Mycobacterium tuberculosis* and fungus.

Turnaround time – Result available one to two working days after receipt.

Mycology

In suspected dermatophyte infections, send skin scrapings, hair or nail clippings.

Turnaround time – Microscopy one working day, culture up to four weeks.

Serology, bacterial, viral, parasite and fungal

For all serological procedures it is important that all relevant clinical details including the date of onset of symptoms, and any risk factors are stated on the request form.

Samples will be processed according to the details stated on the form or in line with laboratory protocol.

The following tests are available on-site :

- Syphilis serology (*Treponema pallidum* antibodies)
- *Helicobacter pylori* serology
- ASO titre
- *Toxoplasma gondii* Total antibody (IgM,IgG) (screening assay)
- Hepatitis B virus surface antigen and antibody
- HBcore Total (IgM, IgG)
- Hepatitis A virus IgM and Hepatitis A Total antibody (IgM, IgG)
- CMV IgM & IgG
- Hepatitis C virus antibody
- HIV 1 & 2 antigen/antibody
- Rubella virus IgG
- Rubella virus IgM
- Varicella-zoster virus IgG (to check for immunity to chicken pox)
- Measles IgG

In house assays are generally available three to four days from receipt.

Many other serological tests are referred to specialist laboratories e.g. Colindale HPA. The following are some of the commonly requested specialist investigation:

- Amoebic serology
- Aspergillus serology
- Atypical pneumonia screen
- Avian precipitins
- Borrelia serology
- Bartonella serology
- Cryptococcal serology
- Hydatid serology
- Leptospira serology
- Mumps serology
- Parvovirus B19 serology
- Schistosoma serology
- Staphylococcal serology
- Toxocara serology

Any enquiries regarding specialist investigations please contact the laboratory on ext. 5251. All serological tests require clotted blood samples.

In case of any molecular investigations such as HIV, HBV and HCV viral loads, CMV PCR, and neonatal HIV diagnosis, EDTA sample is required (see specimen requirements and containers section below).

Turnaround time for sendaway serology – generally 10-14 days from receipt in laboratory.

Mycobacteria, microscopy and culture

Sputum: Auramine staining for Acid Fast Bacilli (AFB) – if urgent, this test can be made available within a few hours. Three sputum samples should be sent preferably the first sputum expectorated each morning for three consecutive days.

Urine: When sterile pyuria is noted, three early morning urines (EMU) should be collected in the containers available from the laboratory.

Biopsy specimens, sterile fluids (CSF, pleural fluid) etc. should be sent in sterile containers to the laboratory.

Molecular technologies: available in reference laboratories for rapid detection of genetic material of *Mycobacterium tuberculosis*. Contact laboratory for further information.

Turnaround time – Microscopy one working day; culture up to eight weeks.

Positive culture and auramine film results will be telephoned immediately.

Antibiotic assays

Assays for gentamicin and vancomycin are available on-site. Antibiotic assay protocol available on the Intranet. Contact the consultant microbiologist for advice if necessary.

Turnaround time – within a working day. Preliminary results will be phoned to the doctor or a senior staff member as soon as the tests are completed.

Procurement of consumables

From Stores

Swabs for bacterial culture (blue-caps)
Blood culture bottles
Universal containers (MSU pots)
Sputum containers
Faeces containers
Hospital Request forms (no absorbent pad)
GP Request forms (with absorbent pad)

Directly from Microbiology

EMU pots for AFB
Per-nasal swabs
Chlamydia trachomatis detection swabs
Herpes simplex detection swabs
Viral culture swabs
Dermapak

Specimen requirements and containers

Urine MC&S	Universal. 10-20ml clean catch
Urine AFB	Special 500ml plastic pot with instructions from Microbiology. Entire EMU
Stool C&S	Universal half filled
Stool OCP	Universal half filled
Enterobius microscopy	Sellotape slide. *Enterobius vermicularis*, the pin worm, lay its' eggs around the anus at night. The eggs are invisible to the naked eye. Dab the sticky side of a length of sellotape onto the anus early in the morning. Stick the tape to one side of a glass microscope slide keeping the tape as flat as possible. Slides and slide boxes available on request.
Sputum C&S	60ml pot quarter filled
Sputum AFB	60ml pot quarter filled
Nasopharyngeal aspirate C&S	Mucus Specimen Set. Remove tube assembly, replace with cap provided and send the Universal only
Blood culture	See Appendix III
Swabs C&S, Wound; Throat; Nose; Vaginal**	"Sterilin" plain transport swab
** *if gonorrhoea suspected*	"Sterilin" charcoal swab
Skin scrapings for mycology	"Dermapak" if available or Universal. Send as much material as possible
Aspirates, body fluids, pus etc	Universal, 20ml maximum

Cerebrospinal fluid MC&S	Sterile universals X 3. Ist and 3rd to Microbiology 2nd universal to Biochemistry (approximately 0.3ml CSF) for protein estimation PLUS 1 fluoride oxalate bottle (approximately 0.2ml CSF) for glucose estimation and 1 fluoride oxalate bottle (blood) for blood glucose estimation.
General viral serology***	5ml clotted blood in plain tube.
HIV antibodies	5ml clotted blood in plain tube.
CMV PCR	5ml blood in EDTA
CMV (in urine)	Universal, half filled
RSV	Nasopharyngeal aspirate in universal
Viral swabs for culture	Green topped "MW&E" swab from Microbiology. Issued only on authorisation of Consultant Microbiologist
Chlamydia (genital infections)	"GenProbe" chlamydia swab available from Microbiology
Chlamydia (eye infections)	Corneal smear slide
Gentamicin & vancomycin assay	See antibiotic protocol on Intranet Clinical Home Page – Monitoring Gentamicin and Vancomycin levels.
HIV viral load	7-8ml blood in EDTA
Meningococcal & Pneumococcal PCR	1-2ml blood in EDTA
Legionella & pneumococcal urinary antigen	Universal 10-20ml clean catch
Herpes simplex	Swab from vesicle fluid in 1ml HSV transport medium from Microbiology
Rotavirus & Clostridium difficile toxin	Faeces in Universal container half filled
HIV maternal transmission	1-2ml blood in EDTA

***For most viral serology paired sera are required, an acute, as early during the illness as possible and a convalescent 10 days afterwards.

Because of the large number of serological tests and groups of tests and the number of different reference laboratories to which they are sent it is not possible to state exactly the volume of serum required. Please telephone ext. 4814.

Reference laboratories

Reference laboratories to which work is routinely referred

Anaerobe Reference Laboratory, NPHS Microbiology Cardiff, University Hospital of Wales, Heath Park, Cardiff . CF14 4XW
CAMR, Porton Down, Salisbury, Wiltshire, SP4 0JG
Clinical Microbiology and HPA, Collaborating Laboratory Brucella Reference Unit (BRU), University Hospital Aintree, Lower Lane,Liverpool. L9 7AL
Enteric, Respiratory & Neurological Virus Laboratory, Health Protection Agency, 61, Colindale Ave. London NW9 5HT
Laboratory of Enteric Pathogens, Health Protection Agency, 61, Colindale Ave. London NW9 5HT
Health Protection Agency, Addenbrookes Hospital, Cambridge. CB2 2QW
Health Protection Agency, Bowthorpe Rd, Norwich
Health Protection Agency, PO Box 209, Manchester Royal Infirmary, Clinical Sciences Building, Manchester. M13 9WZ
Hospital for Tropical Diseases, University College Hospital, Mortimer Market.
HPA Mycobacterium Reference Unit, Clinical Sciences Research Centre, Barts and The London Queen Mary's School of Medicine and Dentistry, 2 Newark Street, London, E1 2AT
Laboratory of Hospital Infection, Health Protection Agency, 61, Colindale Ave. London NW9 5HT
Leptospira Reference Unit, Microbiology, County Hospital, Hereford, HR1 2ER
Meningococcal Reference Unit, Health Protection Agency, PO Box 209, Manchester Royal Infirmary, Clinical Sciences Building, Manchester. M13 9WZ
Microbiology Laboratory, Royal Preston Hospital, Sharoe Green Lane North, Fulwood, Preston, Lancashire, PR2 9HT
Microbiology, County Hospital, Hereford, HR1 2ER
Antimicrobial Reference Laboratory, Department of Medical Microbiology North Bristol NHS Trust Southmead Hospital Bristol BS10 5NB
Mycology Ref **Lab,** SouthWest HPA Laboratory, Myrtle Road, Kingsdown, Bristol BS2 8EL
Mycology Reference Laboratory, Health Protection Agency, General Infirmary, Leeds LS1 3EX
NPHS Microbiology Cardiff, University Hospital of Wales, Heath Park, Cardiff CF14 4XW
Respiratory & Systemic Infection Laboratory, Health Protection Agency, 61, Colindale Ave. London NW9 5HT
Sexually Transmitted & Blood Borne Virus Laboratory, Health Protection Agency, 61, Colindale Ave. London NW9 5HT
Southampton Laboratory Level B, South Laboratory Block, Southampton General Hospital, Southampton SO16 6YD
SouthWest HPA Laboratory, Myrtle Road, Kingsdown, Bristol BS2 8EL
The Hospital for Tropical Diseases, Mortimer Market Building, Capper Street, Tottenham Court Road, London WC1E 6AU
Toxoplasma Reference Laboratory (TRL), Singleton Hospital, Sketty,Swansea, SA2 8QA

SUMMARY OF BACTERIOLOGY SAMPLES AND ASSOCIATED TURNAROUND TIMES

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
SWABS Routine bacterial culture	Swab – (Blue Cap) Containing transport medium		Minimum 2 working days
PUS , ASPIRATES , TISSUE	Sterile Universal	No formalin	Minimum 2 working days
PUS, ASPIRATES, TISSUE - AFB	As above	No formalin	Microscopy 1-2 working days Culture 6 – 8 weeks
SWAB Whooping cough	Pernasal swab – fine twisted wire swab with small bud	Notify Laboratory before sending	Minimum 5 days
SWAB -Ear	Either routine swab (Blue cap) or fine wire swab with small bud		Minimum 2 working days
MRSA SCREEN	Swab – (Blue Cap)	See Infection Control MRSA Policy	Minimum 1 working day
CONTACT LENS -Routine and Acanthamoeba Culture	Send lens in lens fluid	Acanthaboeba sent to ref lab if requested	Routine – Minimum 2 working days Acanthamoeba – 10 – 14 days
CORNEAL SCRAPINGS	Smear scraping on clean labelled microscope slide and place in slide box . Spread scraping onto Blood agar, Chocolate plate and Sabouraud agar.	Please label slide and plates with patient demographics	Smear available same day if requested Culture Minimum 2 working days
CHLAMYDIA – EYE INFECTION	Smear on slides		1 working day
CHLAMYDIA – OTHER SITES	Special collection kits		5-7 working days (GSTS London)
IUCD's Actinomyces culture	Send in sterile 60ml wide necked container		Actinomyces Minimum 2 weeks
URINE Routine bacterial culture	10 – 20 ml midstream urine in a Sterile Universal	CSUs are of very limited value	1 – 2 working days

URINE - Schistosoma	10 ml terminal urine including last few drops specimen collected around midday	preferably after exercise	1 working day
URINE- Legionella Antigen	10 – 20 ml urine in sterile universal		1 -2 hours
URINE- AFB	3 consecutive early morning samples each in a 350 ml sterile container	Available from Pathology	Culture 6 - 8 weeks
URINE- Pregnancy Test	10 – 20 ml early morning urine		Same day testing
SPUTUM-Routine bacterial culture	Deep cough specimen (Not saliva) in 60ml wide neck sterile container	State if patient suffers from bronchiectasis	Minimum 2 working days
BRONCHIAL ASPIRATE / TRAP	Sealed trap or Sterile universal		Minimum 2 working days
SPUTUM- AFB	Deep cough specimen (Not saliva) in 60ml wide neck sterile container		Microscopy 1-2 working days Culture 6 - 8 weeks
BRONCHIAL ASPIRATE /TRAP AFB	Sealed trap or Sterile universal		As above
NPA-RSV	Place tube containing aspirate in sterile container		1 working day
FAECES - Routine culture & Parasitology	Sterile universal half filled container		2-3 working days
FAECES –For C. DIFFICILE TOXIN A&B	Sterile universal half filled container	Do not send repeat specimens within four weeks if positive	1-2 working days
PERIANAL SWAB IN SALINE-For Threadworm	In preference to sellotape slide use saline moistened swab rubbed over the perianal region early morning before bathing, and placed in a plastic universal containing 2mls saline	Kits available from Client Services	1 working day

MYCOLOGY	Skin scrapes from active edge of lesion Nail scrapes in sterile universal deep enough to include invaded tissue, ideally base of nail. Hair should be plucked to include scalp scales and placed in a sterile universal or 60 ml container.	Universals or brown envelopes Or Dermapak	Microscopy weekly Culture 2 – 3 weeks
CSF for bacteriology / virology	3 sterile universal containers	All 3 specimens to Microbiology Phone laboratory to say sample is being sent.	Microscopy - same day Bacterial Culture 2-3 days Fungal 7 days AFB 6 - 8 weeks
BLOOD CULTURES	Aerobic bottles 8 – 10ml Anaerobic bottles 8 – 10ml Paediatric bottles 1 – 3ml Fungal 8-10ml	Remove the centre portion of the barcode and place on the request form. Blood culture bottles sets available from Pathology Put in Pathology incubator ASAP after collection.	48 hour interim report 5 day final 10 days for suspected bacterial endocarditis
BACTERIAL ANTIGEN TEST	POSITIVE CSF	Performed only in conjunction with a positive finding – it is a confirmation test NOT a diagnostic test. Carried out during the next working day, if indicated	
CHILD ABUSE	Specimen collection protocol available from Woodlands Clinic	For legal reasons each person involved in collection & transportation of the specimens must sign the request form stating their role and date and time (CHAIN OF EVIDENCE)	The laboratory must be informed prior to receipt

3. Serology requests

The department offers a range of serological screening tests and a referral service for investigations not performed 'in-house'.

Serology tests can be used to diagnose infections by assessing the patient's antibody response to a particular infective agent. IgM is the first to rise, and presence is indicative of a present or recently acquired infection. Some IgM tests are available but for other infections tests for IgG are used. The IgG antibody response will usually take 10-14 days to occur (but may sometimes be longer). If the duration of a patient's illness is <10 days then an 'acute' serum sample should be collected at this time and a convalescent sample taken 10-14 days later.

A serological diagnosis can be made when the following can be demonstrated:

- There is an increase in antibody titre from the acute to the convalescent serum samples (usually fourfold or greater).
- A stationary but high antibody titre in both samples.
- A fall in titre of antibodies can be regarded as evidence of recent infection.
- IgM is detected.

The following details should be included with <u>ALL</u> serological requests:

- Date of onset of symptoms.
- Relevant clinical details including history of travel, contact dates and any other appropriate information including vaccination history.
- Risk factors

The laboratory cannot process specimens or interpret the result without sufficient clinical information.

Label all specimens and request forms with HIGH RISK stickers if patient known or suspected to be high risk. For investigation of Blood Borne Viruses a SIGNED request form is essential.

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
Amoebiasis/Hyatid/Schistosomal	5ml clotted blood– red and yellow top	Reference laboratory request – will only be sent if full travel history and risk factors are given	2-3 weeks
ANTI –SPERM ANTIBODIES	5ml clotted blood – red and yellow top		3-4 weeks

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
Amikacin, tobramycin and teicoplanin		Sent to Reference Laboratory	Amikacin and tobramycin available next day if received before 9.30am Teicoplanin next working day (Verbal results)
ASOT	5ml clotted blood – red and yellow top	Fairly non-specific test of limited value	Once per week
Aspergillus precipitins	5ml clotted blood– red and yellow top	Reference laboratory request – risk factors and date of onset must be given.	10-14 days
Atypical Respiratory Screen– Legionella, Chlamydia (Psittacosis), Mycoplasma, Influenza A &B, Q Fever (Coxiella)	Acute and Convalescent serum samples required taken 10-14 days apart. 5ml clotted blood – red and yellow top	If atypical pneumonia is suspected and sputum samples are negative for culture. Sent to Reference laboratory Samples will NOT be sent unless date of onset is given and any travel history. Urine sample for Legionella antigen should be sent if Legionella suspected.	10-14 days
AVIAN antibodies	5ml clotted blood– red and yellow top	Reference laboratory request – risk factors must be given e.g. keeps birds	10-14 days
BRUCELLA ANTIBODIES	5ml clotted blood– red and yellow top	Reference laboratory request – details of travel history must be given as well as risk factors e.g. eating unpasteurised cheese. Date of onset and clinical history must be given.	10-14 days
CAMPYLO-BACTER SEROLOGY	5ml clotted blood – red and yellow top	Reference laboratory request – Please give full clinical details e.g. Guillain-Barre syndrome	10-14 days

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
CAT SCRATCH FEVER (Bartonella)	5ml clotted blood – red and yellow top	Reference laboratory request – Please give full clinical details and risk factors. Please give date of onset and state whether patient is immunocompromi-sed.	10-14 days
CMV IgG/M Screen	5ml clotted blood– red and yellow top. Citrated blood required for PCR	Infection usually only of clinical significance in immunocompromi-sed or pregnant patients.	1-3 days
DENGUE FEVER, RICKETTSIA, HAEMORR-HAGIC FEVER, TYPHUS, WEST NILE VIRUS, SARS etc	DO NOT TAKE SAMPLE without contacting Consultant Microbiology	CONTACT Consultant Microbiologist	
EBV	5ml clotted blood – red and yellow top.	Suggest send sample for Monospot in the first instance. If negative and EBV remains a differential diagnosis send sample for EBV testing.	Tested once per 10-14 days
Enterovirus (including Coxsackie)	5ml clotted blood – red and yellow top.	Reference laboratory request – Please give full clinical details –only available if diagnosis is pericarditis.	1-2 weeks
Haemophilus, Pneumococcal,Tetanus Antibodies		Sent to reference lab	2 weeks
Helicobacter pylori IgG	5ml clotted blood – red and yellow top	Cannot distinguish between current and past infection	Once per week
HEPATITIS A IgG	5ml clotted blood with gel – red and yellow top	Immunity check.	1-3 days
HEPATITIS A IgM	5ml clotted blood – red and yellow top	Transmission usually occurs enterically through: Person to Person contact Ingestion of contaminated food or water	1-2 days during working week. Confirmation from ref lab usually 10-14 days

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
HEPATITIS B Surface Antibody	5ml clotted blood – red and yellow top	Post vaccine	1- 2 days during working week
HEPATITIS B Core Antibody	5ml clotted blood – red and yellow top	Indicator of current or previous HBV infection. Should be requested in cases of household contact. Automatically performed on non-responders to Hepatitis B vaccine.	1-2 days during working week. Confirmation from ref lab usually 10-14 days
HEPATITIS B Surface Antigen	5ml clotted blood – red and yellow top	Transmission routes: Percutaneous, Permucosal, sexual.	1-2 days during working week. Confirmation from ref lab usually 10-14 days.
HEPATITIS C antibodies	5ml clotted blood – red and yellow top	Transmission routes: Percutaneos Permucosal PLEASE NOTE – incubation period is 2-26 weeks.	1-2 days during working week. Confirmation from ref lab usually 1-4 weeks
HERPES SIMPLEX antibodies	5ml clotted blood – red and yellow top	Herpes simplex antibodies of little value in diagnosing current infection. VIRAL SWAB of lesion preferred. Reference laboratory request.	
HERPES SIMPLEX PCR	CSF , Swabs	Sent to reference laboratory. CSF must demonstrate appropriate cellular features to justify test.	2 – 4 working days
HIV 1 & 2 Ag/Ab	5ml clotted blood – red and yellow top Confirmatory sample should be taken in EDTA.	Transmission routes: Percutaneous Permucosal Sexual	1-2 days working days. Confirmation from ref lab usually 10-14 days.
HIV REQUEST NEONATE BORN TO HIV POSITIVE MOTHER	EDTA Sample within 24 hours of birth. Repeat at 6 weeks, 3 months and 6 months.	EDTA sample must also be taken from mother at time of birth so that primers can be checked.	10-14 days

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
LYMES DISEASE – Borrelia burgdorferi	5ml clotted blood – red and yellow top	Reference laboratory request – risk factors such as insect bites and travel history must be given as well as onset and nature of symptoms.	10-14 days
Meningococcal PCR and antibodies	CSF and PLASMA (i.e. EDTA sample) for PCR	PCR request sent to Ref lab if findings indicate risk of infection. Antibody sample should be collected 3 weeks after onset of infection – is only of value for retrospective diagnosis.	PCR 2 – 3 working days Antibody – several weeks
MUMPS antibodies	5ml clotted blood – red and yellow top If current infection is suspected Saliva testing kit should be requested from Colindale 020 8200 6868 ext 4412	Reference laboratory request suitable for 'at risk' contacts of confirmed cases only. Post vaccination antibody levels will not be tested as not appropriate.	10-14 days
NEEDLESTICK INJURIES/ HUMAN BITES etc	5ml clotted blood – red and yellow top	MUST state whether donor or recipient of injury. Should discuss such cases with Consultant Microbiologist and/or CCDC. Hepatitis B antibodies and serum save will be run on recipient's serum. Tests on donor blood will only be run if permission is given.	1-2 days during working week. Service not available over weekend or bank holidays.
PARVOVIRUS IgG / IgM	5ml clotted blood – red and yellow top	Please give full clinical details and date of onset. Sent to reference laboratory	10-14 days.
RUBELLA IgG	5ml clotted bloodl – red and yellow top	Antibody levels >10 iu/ml considered as immune	1- 2 days during working week
RUBELLA IgM	5ml clotted blood – red and yellow top	Please give full clinical details and date of onset of symptoms	3-4 days during working week
SYPHILIS SEROLOGY	5ml clotted blood –		1-3 days

TEST	SAMPLE	COMMENTS	TURN-AROUND TIMES
	red and yellow top		Positives sent to ref lab for confirmation
TOXOPLASMA IgG	5ml clotted blood with gel – red and yellow top.	Animal transmission. Particular concern in pregnancy.	Tested daily Positives sent to ref lab for confirmation
VZV IgG	5ml clotted blood – red and yellow top	Please state whether patient is pregnant or immunocompro-mised. Date of contact MUST be given.	Run daily
VZV IgM – very rarely indicated as Chicken pox is a clinical diagnosis.	5ml clotted blood – red and yellow top	Sent to Reference laboratory. Rarely necessary as Chicken Pox is essentially a clinical diagnosis	Positive results phoned Negative results 10-14 days
WEILS DISEASE – Leptospira antibodies	5ml clotted blood – red and yellow top	Reference laboratory request. Full details of risk factors e.g. sewage worker, ingested river water etc must be given. Date of onset and clinical details also required.	10-14 days

INFECTION CONTROL Advice is available at all times. Infection control policies are available in all wards and departments, and on the intranet.

NOTIFIABLE DISEASES

Acute encephalitis
Acute poliomyelitis
Anthrax
Cholera
Diphtheria
Dysentery (amoebic or bacillary)
Food poisoning (or suspected food poisoning)
Leprosy
Leptospirosis
Malaria
Measles
Meningitis (viral, bacterial or fungal)
Meningococcal septicaemia
Mumps
Ophthalmia neonatorum
Paratyphoid fever
Plague
Rabies
Relapsing fever
Rubella
Scarlet fever
Smallpox (eradicated in 1979)
Tetanus
Tuberculosis
Typhoid
Typhus
Viral haemorrhagic fever
Viral hepatitis (A,B,C,D,E)
Whooping cough
Yellow fever

5. Cellular pathology

Cellular pathology comprises histology and cytology.The laboratory offers the following services:

Histopathology

Histopathology provides a comprehensive tissue diagnostic service to Bedford Hospital and local general practitioners, including immunocytochemistry and referral for molecular diagnostics. Also provides tissue diagnosis for the Bowel Cancer Screening Programme.

Cervical cytology

The cytology dept. provides the NHSCSP cervical screening service for Bedfordshire PCT, and since April 1st 2010 has provided the same service for NHS Luton PCT, processing and screening in excess of 39000 cervical liquid based cytology specimens annually.

Diagnostic cytology

Cytopathology also provides a comprehensive Fine Needle Aspiration (FNA) and diagnostic cytology service.

This includes evaluation of body cavity fluids, and washings and brushings from various sites in the body.

Fine needle aspiration cytology

This is a quick, minimally invasive and cost-effective method of reaching a cellular diagnosis on mass lesions. The consultant cytopathologist offers an on-demand FNA service.

Semen analysis

This includes routine semen analysis for infertility cases as well as evaluation of post-vasectomy specimens.

Key contacts

	External	Internal
Dr M Wilkins. Consultant Histopathologist	01234 792094	4729
Dr K Adu-Poku. Consultant Histopathologist	01234 355122 x 4731	4731
Dr J Patel. Consultant Histopathologist	01234 355122 x 4730	4730
Mr N Cully, Specialty Manager, Cellular Pathology	01234 792092	4694
Dr F Mutch. Consultant Cytopathologist	01234 792325	4725
Hospital Based Co-ordinator, Cytology, Advanced Practitioner	01234 355122 x 4734	4734
A&C Office		
Mrs A Strong, A&C Manager	01234 792628	4658
Histology enquiries	01234 792149	4607
Cytology enquiries	01234 355122 x 4611	4611

Opening times

	Enquiries	Specimens
Monday to Friday	8.30 am - 5.00 pm	8.30 am - 4.30 pm

During working hours, specimens are to be delivered to the 2nd floor laboratory. Specimens can be left at the Specimen Reception Desk situated on the First Floor of the Pathology Block off the main corridor of the Hospital when the Cellular Pathology Department is closed.

User satisfaction and complaints

Cellular pathology is pleased to receive constructive comments upon any aspect of its services.

A quality manual describing all aspects of the department's quality management system is available for inspection by users.

Completion of histology and cytology request forms

All sections of the request form must be completed. Without this information appropriate examination may not be instituted and interpretation of results may be impossible or misleading.

Specimen and request card labelling

It is essential that specimens are correctly identified. A minimum of three points of ID is mandatory.

All specimens must be labelled with:

- The patient's full name
- Date of birth
- Hospital or NHS number
- The date of specimen.
- Type of specimen

Inadequately labelled specimens will not be examined.

In the case of unlabelled, unrepeatable, specimens such as most histology samples, CSF, etc the requesting doctor will be given the opportunity to identify the specimen and asked to sign to accept responsibility for identification.

Identification of high risk specimens

For the protection of laboratory workers the request form and any specimens collected from a patient with a known **or suspected** infection due to a Hazard Group 3 biological agents must be labelled as 'high risk'. These agents include:

HIV 1 and 2
Hepatitis B virus
Hepatitis C virus
Brucella spp.
Salmonella typhi & paratyphi
Mycobacterium tuberculosis
HTLV 1 and 2

and the causative agents of: -

Anthrax
Rabies
Plague
Creutzfeldt-Jakob disease
Yellow Fever

Histology laboratory

Surgical pathology

Fixation

The tissue fixative used routinely is **formalin** (10% neutral buffered formalin solution). On request, labelled specimen containers of various sizes, containing formalin, are provided by the laboratory to all users as required.

All tissue samples should be placed in fixative as soon as possible after removal from the patient. With small biopsies in particular, it is important not to let the specimen dry out. The recommended volume of fixative is at least ten times the volume of the specimen, so it is important not to squeeze a specimen into too small a container. If in doubt, choose a larger container. Poor fixation can hinder or prevent accurate histological diagnosis.

The temptation to slice open or dissect an excised specimen before it is sent to the histopathology department should be resisted. Subsequent fixation of a partly incised specimen may cause distortion and hinder anatomical orientation. In the case of excised tumours, it may then be impossible to identify surgical planes of excision.

Containers of formalin should be securely closed and users are recommended to read the Trust policy on the transport of specimens in formalin. Formaldehyde vapour is a well-recognised respiratory irritant. Skin contact with formalin solution should be avoided, as repeated exposure may cause dermatitis in some individuals.

On no account should unfixed specimens be sent to the histopathology laboratory without prior consultation with one of the consultant histopathologists.

SAMPLES IN FORMALIN MUST NOT BE SENT VIA THE PNEUMATIC TUBE SYSTEM.

Turnaround times

Urgent results can be available within 48 hours. Biopsy reports are generally available 48 hours from receipt of the specimen. Routine results are usually available within three to five working days. Complex specimens and specimens requiring further investigation may take longer.

Most small specimens will be reported in three to five days.
Most larger specimens will be reported in five to seven days.

Specimens containing bone:

Bone Marrow Trephines require decalcification and the **minimum** turnaround time for a report is five days.

Other specimens, which contain bone will take longer than one week.

Cytology laboratory

1. **Cervical cytology – Liquid Based Cytology (LBC) samples**
2. **Diagnostic Cytology - Cytology of fluids and aspirates**

Note that NHS Luton and NHS Bedfordshire as local purchasers of the cervical screening programme determines the policy on cervical screening, including interval between smears.

The laboratory actively manages inadequately labelled samples, late deliveries of samples, and out of programme samples in order to ensure patient safety and to deliver the 14 day patient pathway.

Out of programme samples which cannot be processed by the laboratory are:

3. Patient is under 24.5 years old and not scheduled from a previous test
4. Patient on three yearly recall and sample received less than 30 months since previous routine negative test
5. Patient on five yearly recall and sample received less than 54 months since previous routine negative test
6. Patient aged 65 and over with 3 consecutive routine negative tests, 2 of which were in the last 10 years
7. This sample is not clinically appropriate

Liquid based cytology

Procedure for submitting a liquid based cytology sample:

Equipment: request form
LBC vial with collection fluid (pre-filled)
Cervibrush

The vial must be clearly labelled with the patient's **surname, forename, date of birth** and **NHS number or Hospital number.**

After taking the sample with the Cervibrush, **place brush in vial and agitate** to ensure all the cervical material is released into the fluid. **Remove brush** and send vial to laboratory. Vials are transported to the laboratory in transport boxes provide by the hospital courier.

Sample takers are requested to submit the sample with an A5 size HMR101 request form generated by the Open Exeter computer system. Instructions for printing the correct format of HMR101/5 form from Open Exteter are available on request from the cytology department. If senders are unable to print the HMR101 form then request forms are available from the cytology dept. Request forms must be completed in full. This includes **name** and **previous names, address, date of birth, NHS number, reason for the smear, sender and source details, time and date of test** and any **relevant clinical information**.

Relevant clinical information includes any history of CIN and previous biopsy results. If the patient has had a hysterectomy please indicate the reason as this will determine the need for further vault samples.

The laboratory works to all guidance and protocols issued by the NHS Cancer Screening Programmes, including those found in the following publications:

Achievable Standards, Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology. *NHSCSP Publication No.1 Second edition including revised performance indicators May 2000*

Guidelines on Failsafe Actions for the Follow-up of Cervical Cytology Reports *NHSCSP Publication No 21 December 2004*

Audit of Invasive Cervical Cancers. *NHSCSP Publication No 28 (Dec 2006)*

Please Note: Copies of NHS Cervical Screening Publications can be obtained from:-

The Department of Health Publications Orderline
Tel: 08701 555 455
Fax: 01623 724 524
Email: doh@prolog.uk.com

Copies are also available as PDF files on the NHS Cancer Screening Programme website – www.cancerscreening.nhs.uk.

2. Diagnostic cytology

The laboratory processes a wide variety of specimens, much of which is unfixed and requires processing promptly to prevent deterioration of the cells. **Specimens should therefore be sent to the laboratory without delay.**

All specimens must be labelled with the patient's full name and date of birth and accompanied by a request form that has been completed in full. Request form and specimen should be delivered to the cytology laboratory in plastic transport bags.

High risk specimens must be labelled as such to ensure that laboratory staff when handling these specimens take appropriate precautions.

Body fluids e.g. pleural fluid, ascites, synovial fluid, hydrocoele fluid, breast cyst fluid should be put in a dry 60ml plastic specimen container. Please provide at least 25ml of fluid from body cavity fluids to enable full analysis to take place, including immunocytochemistry when appropriate.

Urine samples need to be fixed as the cells deteriorate very quickly in urine. The specimen should be put in a plastic specimen container a small amount of preservative (formalin). Pre-prepared urine pots are available from the cytology laboratory or pathology laboratory reception (South Wing, GSTS Pathology building, floor 1). Three specimens of urine should be collected on three consecutive days. A mid-morning urine rather than the first urine of the day is the best specimen to send for cytological investigation. Patient instruction sheets are available from the cytology department on request.

Sputum. Specimens of early morning “deep cough” sputum should be submitted on three consecutive days. The specimens should be put in a 60ml. plastic specimen container.

Further advice on any aspect of specimen collection, transport, or suitability for examination can be obtained from the cytology laboratory, (01234) 792623.

- Please note. Cells degenerate rapidly. Samples for cytological examination must be sent to the laboratory as soon as possible.
- Any high- risk specimens, e.g. HIV infection, Hepatitis B or C, should be identified clearly on both the sample and request form.

Results

Diagnostic cytology reports are typically available twenty-four to forty-eight hours from receipt of the specimen.

Andrology service

In order to enable improvements to the andrology service the cellular pathology department at Bedford Hospital NHS Trust introduced an appointment system for its Infertility semen sample analysis on August 1st 2011.

From this date the Infertility semen analysis service **runs between the hours of 09.00 and 13.00 Monday to Wednesday by appointment only**.

How to book an appointment:

Send a pathology request form, clearly stating "semen analysis for infertility" to:

Appointments Office, Administration and Clerical Office, GSTS Pathology, Bedford Hospital, Kempston Rd, Bedford MK42 9DJ.

Please ensure the correct and full patient address is included on the request form.

On receipt of the form, the laboratory will post a patient information sheet and sample pot to the patient and will allocate the next available appointment date, but allowing a fortnight for delivery of the information. A contact telephone number will be provided to allow the patient to rearrange the appointment date if it is inconvenient. The patient may bring the sample to the laboratory at any time between 09.00 and 13.00 on the appointed date. The sample should be delivered **within one hour** of production. Please note that there are NO facilities on-site for sample production.

Following analysis if all values are within reference ranges then no further appointments will be issued by the laboratory. If any values are outside reference ranges in the first sample then the laboratory will request a second sample and send a second information sheet and pot to the patient. Once the second sample has been examined and a report issued the laboratory will not request any further samples.

If a patient fails to attend:
A letter will be sent to the requesting clinician and we would ask that contact is made with the patient to ascertain the reason for the non attendance. If the test is still required please send a repeat request to the laboratory at the above address.

If you have any questions regarding the provision of the Andrology service please contact the appointments office, GSTS Pathology on (01234) 792149

Advice for patients:

Please ensure that adequate instruction is given to the patient on production of the semen specimen. **The time of specimen collection must be recorded on the request form and specimen container.**

Semen specimens must be delivered to the laboratory within one hour of production as these samples deteriorate rapidly and results will be impaired, particularly the motility assessment. Please note that there are NO facilities on the Hospital site suitable for the production of semen samples.

Please ensure patients are reminded of the importance of writing the time of specimen production on the request card and specimen container before delivery to the laboratory in addition to general information required for labelling specimen containers and request cards. The patients are asked to remain in the pathology specimen reception area for a short while after delivering the sample pot and form to ensure all information required has been provided.

Instructions to patients:

The following information is provided by the laboratory to patients:

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Patient instructions and helpful information

Please produce the sample at home, carefully following the instructions provided below.

You should abstain from sexual intercourse or masturbation for a minimum of two days and a maximum of seven days before producing the sample for examination; this will ensure the sperm are at their best for testing.

The specimen must be produced by masturbation (stimulation by hand) directly into the specimen container provided. It is very important that only the container provided is used as this has been confirmed as being suitable for the test. Do not use an ordinary condom to collect the sample, or use lubrication, as either will seriously affect the test results.

It is important that the entire sample is collected in the specimen pot. If any of the sample is lost please telephone the laboratory on the number provided to arrange a repeat test on a convenient date.

Ensure the lid is tightly secured, and record your surname, forename, date of birth and date / time of sample collection on the pot.

Keep the sample warm, for example in an inside pocket, during delivery to the department. Excessive heat (greater than 40C) or excessive cold (below 20C) will seriously affect the test result.

The sample must be delivered to the laboratory as soon as possible, but within one hour of production to ensure the sample is received at its best. Please note there are no suitable facilities at Bedford Hospital in which to produce the sample.

Please deliver the sample pot and this form to:

Pathology specimen reception,
Floor 1, GSTS Pathology,
South Wing, Bedford Hospital,
Kempston Road, Bedford
MK42 9DJ.
Tel: 01234 792149

On delivering the sample we would appreciate if you could wait a short time at the specimen reception to ensure the information on your paperwork and pot are completed before leaving the laboratory.

The sample will be examined immediately on receipt by the laboratory and the result will be sent to the requesting doctor within seven days. Please do not telephone the laboratory for results as we are not authorised to give results to patients directly.

The laboratory examines the sample and reports it according to the latest reference ranges. If any parameters are outside the reference ranges, or if the laboratory is unable for technical reasons to complete all test, a repeat sample will be requested by the laboratory and you will receive a pot and new documentation for this in the post.

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Copies of the above instructions for patients are available from the laboratory on request.

Reporting of semen samples:

Semen reports for the investigation of infertility include the following:

- Sample volume,
- pH,
- assessment of viscosity,
- presence of agglutination or aggregation of sperm,
- sperm concentration,
- total number of sperm in the sample,
- assessment of sperm motility and of sperm morphology.

It is helpful to include the name of the partner and the NHS/Hospital number on the request form for the correlation of results from both partners. If provided, this will be included on the report.

Recommendations for measurements and reference values for semen analysis in infertility investigation have been made by the World Health Organisation (WHO), whose standards are employed by most andrology laboratories. WHO recommendations changed in 2010 and this laboratory reports semen samples in line with the current WHO recommendations (5^{th} Edition).

Reference ranges for human semen samples

The following normal reference ranges are used for human semen:

1. Motility

Sperm motility is assessed in four categories and the percentage falling into each category calculated. The categories of motility are:

A. Rapid progressive
B. Slow/sluggish progressive
C. Non-progressive
D. Non-motile

The normal reference ranges are:

Progressive sperm motility (A+B) : >32%
Total sperm motility (A+B+C) : >40%

2. Morphology

Sperm morphology is assessed against published WHO criteria and the percentage of **normal** forms reported.

WHO guidelines recommend a lower reference range of 4% normal forms.

3. Other values:

Semen volume:	>1.5ml
Total number of sperm in ejaculate:	>39 Million
Sperm concentration:	>15 Million per ml
Sperm vitality (live sperm)	> 58%
pH:	>7.2

ref: WHO laboratory manual for the examination and processing of human semen (5th Ed.).

If you have any queries regarding semen analysis for infertility investigation, please contact the andrology service manager, histology dept.

Post vasectomy sample analysis:

The introduction of the appointment system does not affect the service for routine post vasectomy samples. These can be delivered to the laboratory at any time between 09:00 and 14:00 Monday to Friday.

Advice for patients for the production of semen samples for post vasectomy analysis.

The following advice is issued to patients for routine post vasectomy semen analysis

Instructions to patients:

1. The sample should be produced by masturbation into the container provided. No other container is suitable for this test. It is important not to use either a condom or any type of lubricant as these will seriously affect test results.
   It is important the whole sample is collected in the pot. If any sample is lost then it will not be suitable for assessment and a further sample will be required on another occasion. If this is the case please contact the laboratory on the telephone number below.

2. The container must be labelled with:
   Your full name
   Your date of birth
   Your NHS number and / or Hospital number
   The Date and Time of production of sample

   Please ensure the lid is properly secured to stop leakage of sample from the pot.
   The specimen pot should be kept warm i.e. in an inside pocket whilst in transit to the hospital. Excessive cold or heat must be avoided as either will affect the test results.

   The form and pot should be brought to the ***Pathology Specimen Reception on Floor 1 of GSTS Pathology, Pathology Building, Bedford Hospital South Wing within one hour of production.***

   The samples are accepted between the hours of 9am and 2pm Monday to Friday

3, **Please note there are no facilities at the hospital site to produce semen samples.**

If you have any questions, please telephone pathology (01234) 792149, between 9am and 5pm.

Copies of the above instruction sheet are available from the histology dept on request.

Fresh post vasectomy samples. If a patient has four or more post vasectomy semen samples showing the persistence of sperm then it is recommended that a full analysis of a fresh post vasectomy sample, including an accurate assessment of sperm concentration and motility, is undertaken and the above appointment system should be used for this. If a *fresh* post vasectomy analysis is required please send a request form to the above address clearly requesting “fresh post vasectomy analysis” following which an appointment will be sent by the laboratory in the same way.

Post vasectomy reversal samples: Patients requiring testing of semen following a post vasectomy *reversal* procedure should submit a sample via the appointment system to allow full analysis of a fresh sample. A request form should be sent to the appointments office indicating “post vasectomy reversal semen analysis”, following which an appointment will be made for submission of a sample.

6.**Patient information sheets**

The following patient information sheets are available on the Bedford Hospital site, *www.bedfordhospital.nhs.uk/clinical-biochemistry*

- Appointment for a Glucose Tolerance test

- Patient instructions for Collecting a 24 hour urine sample.

- Patient instructions for Collecting a 24 hour urine sample for HMMA (VMA) Catecholamines, Metadrenalins and 5HIAA